

UNITED STATES DEPARTMENT OF DEFENSE

DEFENSE HEALTH BOARD MEETING

DAY 2

Arlington, Virginia

Friday, September 5, 2008

ANDERSON COURT REPORTING
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1 P R O C E E D I N G S

2 DR. POLAND: Good morning, everybody.
3 The agenda has been slightly altered, primarily
4 because the Deployment Health Research Center,
5 External Review, and Health Implications for
6 Prisoners of War was accomplished yesterday. So
7 we're going to follow our current agenda down to
8 11:00, and then the Board will go into an
9 Executive Session.

10 So we have a lot to do today, this
11 morning, so we'll get started. Ms. Embrey, could
12 I ask you to call the meeting to order, please?

13 MS. EMBREY: Absolutely, my pleasure.
14 As the designated federal official for the Defense
15 Health Board, a Federal Advisory Committee and a
16 continuing independent scientific advisory body to
17 the Secretary of Defense and to -- via the
18 Assistant Secretary of Defense for Health Affairs,
19 and the Surgeon Generals of each of the military
20 departments, I hereby call this meeting of the
21 Defense Health Board to order.

22 DR. POLAND: Thank you; and again,

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1 carrying on the tradition of our Board, if I could
2 ask everybody to stand for a moment of silence to
3 honor our service men and women.

4 (Moment of silence.)

5 DR. POLAND: Thank you all very much.
6 Since this is an Open Session, as we did
7 yesterday, I'd like to go around the table, have
8 the Board and distinguished guests introduce
9 themselves. And one other comment is to any
10 members of the public that would like to make
11 statements during the session today, and I believe
12 we have some regarding at least two of our agenda
13 items. Could I ask you to please register or sign
14 in with Lisa, who I gather is probably out at the
15 table. Okay.

16 Oliver, if you could raise your hand,
17 too. She's also available to assist you. So
18 maybe, if we could, I'll go the opposite way
19 today, start with Colonel Gibson, and have people
20 introduce themselves.

21 COLONEL GIBSON: Colonel Roger Gibson,
22 I'm the Executive Secretary for the Defense Health

1 Board.

2 MR. UNTERMEYER: I'm Chase Untermeyer, a
3 private business man in Houston.

4 MR. O'LEARY: Dennis O'Leary, President
5 of Emeritus, The Joint Commission.

6 DR. PARKINSON: Dr.Mike Parkinson, I'm
7 the President of the American College of
8 Preventative Medicine.

9 DR. PARISI: Dr.Joe Parisi from Mayo
10 Clinic, I'm a neuro pathologist, and also Chair of
11 the Subcommittee and Pathology and Laboratory
12 Services for the DHB.

13 DR. ERDTMAN: Good morning, I'm Rick
14 Erdtman, the Director of the Board on Military and
15 Veterans Health at the Institute of Medicine.

16 DR. SHAMOO: Adil Shamoo, Professor and
17 former Chair, University of Maryland School of
18 Medicine, I'm Bioethisist.

19 DR. HALPERIN: Bill Halperin, Chair,
20 Preventive Medicine, New Jersey Medical School,
21 Newark.

22 DR. KELLY: Jim Kelly, Neurologist at

1 the University of Colorado and Chair of the
2 Traumatic Brain Injury External Advisory
3 Subcommittee.

4 DR. BLAZEK: I'm Dr. Bill Blazek, I'm a
5 -- at Georgetown University in the Center for
6 Clinical Bioethics, and I'll be in the
7 Subcommittee on Medical Ethics, Health Care
8 Ethics, thank you.

9 DR. MULLICK: I'm Dr. Florabel Mullick,
10 Director of the Armed Forces Institute of
11 Pathology, and also Executive Secretary of the
12 Scientific Advisory Board for Pathology and
13 Laboratory of the Defense Health Board.

14 COMMANDER SLAUNWHITE: I'm Commander
15 Cathy Slaunwhite, a Canadian Forces Medical
16 Officer in a liaison role at the Canadian Embassy
17 in Washington, D.C.

18 COMMANDER FEEKS: Good morning; I'm
19 Commander Ed Feeks, Preventative Medicine, Officer
20 at Headquarters, Marine Corps.

21 CAPTAIN NAITO: Captain Neil Naito,
22 Director of Public Health, Navy Medicine.

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1 COLONEL MOTT: Colonel Bob Mott,
2 Preventative Medicine, Officer at the Army Surgeon
3 General's Office.

4 LT. COLONEL BLEDSOE: Yolanda Bledsoe,
5 Health Service Support Division at the Joint
6 Staff.

7 LT. COLONEL GOULD: Phil Gould, Air
8 Force Medical Operations Agency.

9 CAPTAIN COWAN: Group Captain Alan
10 Cowan, I'm the British Liaison Officer to the
11 Office of the Assistant Secretary of Defense for
12 Health Affairs, Forced Health Protection and
13 Readiness. Try saying that if you had a drink.
14 I'm also the British Liaison Officer to the
15 Veteran's Administration.

16 DR. KAPLAN: Good morning; I'm Ed
17 Kaplan, Professor of Pediatrics, University of
18 Minnesota Medical School.

19 DR. MILLER: I'm Mark Miller, Director
20 for Research at the International Center at the
21 NIH.

22 DR. BLAZER: I'm Dan Blazer,

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1 Psychiatrist at Duke, Epidemiologist, as well.

2 DR. GARDNER: I'm Pierce Gardner, I am a
3 Professor of Medicine in Public Health at the
4 University of New York at Stony Brook.

5 DR. OXMAN: I'm Mike Oxman, Professor of
6 Medicine and Pathology at the University of
7 California San Diego, and an ID doc and
8 virologist.

9 DR. BENJAMIN: Good morning; my name is
10 Richardean Benjamin, I'm the Chair of the School
11 of Nursing at Old Dominion University in Norfolk,
12 Virginia.

13 DR. LaNOUE: And I'm Alcid LaNoue, DR.,
14 Orthopedic Surgeon, former Army Surgeon General,
15 retired since '96, special interest in
16 amputations.

17 DR. SILVA: Joseph Silva, Professor of
18 Internal Medicine, Infectious Diseases, and Dean
19 Emeritus, University of California, Davis School
20 of Medicine.

21 DR. WALKER: David Walker, Chair of
22 Pathology at the University of Texas Medical

1 Branch and Executive Director of the Center for
2 Biodefense and Emerging Infectious Diseases in
3 Galveston.

4 DR. DETRE: Thomas Detre, Professor of
5 Psychiatry and former Senior Vice Chancellor for
6 Health Sciences, University of Pittsburgh.

7 DR. CERTAIN: Robert Certain, retired
8 Air Force Chaplain, Episcopal Priest serving in
9 Marietta, Georgia.

10 DR. KELLEY: Joe Kelley, Deputy
11 Assistant Secretary for Clinical and Program
12 Policy.

13 DR. LUEPKER: Yes, I'm Russell Luepker
14 and I'm a Professor of Epidemiology and Medicine
15 at the University of Minnesota.

16 DR. LEDNAR: Wayne Lednar, Global Chief,
17 Medical Officer, Dupont.

18 DR. WILENSKY: Gail Wilensky, Economist,
19 Senior Fellow at Project Hope.

20 MS. EMBREY: Ellen Embrey, Designated
21 Federal Official.

22 DR. POLAND: Greg Poland, Professor of

1 Medicine and Infectious Diseases at Mayo Medical
2 School in Rochester, Minnesota.

3 MR. DINIEGA: Ben Diniega, Health
4 Policy, Analyst, Health Affairs.

5 DR. CAMERON: Dr. Daniel Cameron, I'm an
6 Internist in private practice, Epidemiologist, and
7 also from the University of Minnesota, and I'll be
8 talking about Lyme Disease today.

9 MS. JOVANOVIC: Olivera Jovanovic,
10 Support Staff, Defense Health Board.

11 MS. BADER: Sarah Bader, Defense Health
12 Board Support Staff.

13 MS. BASU: Sandra Basu, writer with U.S.
14 Medicine.

15 MR. CAMPBELL: Joe Campbell, UK --
16 Office of the Army Surgeon General.

17 MR. DRABEL: Ray Drabel, Armed Forces
18 Institute of Pathology.

19 MR. PERRY: Michael Perry, Director of
20 Operations for the American Registry of Pathology.

21 MS. STOMBLER: Robin Stomblер with
22 Auburn Health Strategies.

1 DR. LIPSITZ: Robert Lipsitz,
2 Preventative Medicine Physician.

3 DR. MOORE: Thomas Moore, Preventative
4 Medicine, Resident, Uniformed Services University.

5 DR. BELLAN: Chris Bellan, Preventative
6 Medicine, Resident, Uniformed Services.

7 MR. BAKER: Tom Baker, I'm the Chief of
8 the Integrated Department of Pathology at Walter
9 Reed Army Medical Center and National Naval
10 Medical Center.

11 MR. LARSON: David Larson, I'm the Lab
12 Director at the National Naval Medical Center and
13 I'm the Specialty Leader for Pathology for the
14 Navy.

15 MS. GERZ: Martha Gerz, Joint Task
16 Force, CapMed, Clinical Operations.

17 MS. JEFFS: Barb Jeffs, JTF, CapMed,
18 Health Care Delivery Operations.

19 MR. CARNE: Bill Carne, Department of
20 Public Health at Brook City Base, Texas.

21 MR. DEALE: Tim Deale, Deputy Chief at
22 NSA Medical Center.

1 MR. THOMPSON: Donald Thompson, I'm at
2 the Defense Department, Office of the Inspector
3 General.

4 MR. LAUDER: Dave Lauder, Neonatologist,
5 Director of Medical Operation Policy, Air Force
6 Surgeon General.

7 MR. WEBB: Mark Webb, Army Surgeon
8 General's Office.

9 MR. BERNETT: Dan Bennett, Program
10 Director at the General Preventative Medicine
11 Residency at USUHS.

12 DR. POLAND: Colonel Gibson has some
13 administrative remarks before we begin our first
14 morning session.

15 COLONEL GIBSON: I want to thank the
16 staff here at the Sheraton Crystal City Hotel for
17 helping with the arrangements for the meeting.
18 And thank you to all of our speakers for all the
19 hard work in putting together the briefings and
20 getting them in on time, on schedule.

21 Also, thanks to my staff, the Defense
22 Health Board Support Staff, for all of the travel

1 arrangements and all of the other business that
2 needs to be done to carry on one of these
3 meetings. I also particularly want to thank Ms.
4 Ward, who's back at our office doing the rest of
5 the administration while we're gone, particular
6 with the subcommittee meetings coming up.

7 Those of you not sitting at the tables,
8 we have handouts that are outside, we'll also be
9 passing out those to the members as needed.
10 Restrooms are located out the door, to the left,
11 and down the hall. This is an open meeting of the
12 Defense Health Board. By Federal Advisory
13 Committee rules, we would very much appreciate if
14 you'd sign in for this. We need to account for
15 everybody who attends the meeting and ensure that
16 that goes into the record for the General Services
17 Administration. Because it's an open meeting,
18 we're transcribing the entire meeting, so please
19 introduce yourself when you speak, speak clear so
20 our transcriptionist can capture everything
21 accurately.

22 Refreshments are available for this

1 morning's session, again, to the left, down the
2 hall, and go around the corner, you'll find them
3 there.

4 We have CME credits for this meeting.
5 The paperwork is either outside on the table, and
6 for the Board members, it's in your books. Lisa
7 can help you with the administration of those.
8 Please turn those in before you leave today.
9 Thank you.

10 The next meeting of the Defense Health
11 Board will be December, tentatively the 11th and
12 12th. We may have to adjust that slightly, a day
13 either way, we'll let everybody know, post it on
14 our web site, as well as send an email to the
15 Board members so they know when it is. And the
16 topics will be related to subcommittee updates,
17 draft recommendations and new business before the
18 Board at that time. The meeting is tentatively
19 scheduled for the Air Force Academy in Colorado
20 Springs.

21 DR. POLAND: Thank you. Our first
22 speaker today is Colonel Thomas Baker of Walter

1 Reed Army Medical Center, who will provide an
2 update on the Joint Pathology Center. Selected
3 members of the Defense Health Board will review
4 the Department's Draft Implementation Plan
5 regarding the establishment of the GAPC and
6 provide comment and recommendations. Colonel
7 Baker's slides are under Tab 9, I believe, yes,
8 Tab 9. We have, I think, 30 minutes scheduled for
9 this.

10 DR. KELLEY: And Doc Poland, just a few
11 introductory comments, a follow-up from the last
12 meeting as Dr. Baker is getting ready; we asked the
13 Board to review a strategic plan for a Joint
14 Pathology Center, and this comes after the
15 direction under the BRAC law for the dis-
16 establishment of the AFIP, and then the last
17 National Defense Authorization Act, which
18 instructed the President to form a Joint Pathology
19 Center within the Department of Defense unless it
20 could not, and then it was to form that Joint
21 Pathology Center under one of the other federal
22 agencies if it could not be done in the Department

1 of Defense. And so at the last meeting, I briefly
2 presented the process, where we went from a large
3 number, six or eight different options, how we
4 came down to three, which ended up with a
5 discussion with this proposal. You can just bring
6 up Dr.Baker's slide, that's fine. And now that
7 has been turned over to the Joint -- to the Joint
8 Task Force to develop an implementation plan, and
9 this is the opportunity to review that
10 implementation plan for comments.

11 The decisions, we've already made the
12 decision that it could be done in the Department
13 of Defense, and so that was the first decision;
14 then the second decision was how, or the
15 structure, and that's going to be described here
16 in the implementation plan.

17 COLONEL BAKER: Thank you, sir. I
18 appreciate the opportunity to come and brief this
19 concept of operations. And this is a -- I believe
20 the entire Board has a copy of our Concept of
21 Operations. And this is kind of a big picture
22 look at our proposal for the Joint Pathology

1 Center, as well as kind of a big picture
2 implementation plan. And as Dr.Kelley noted, this
3 is the purpose of the brief, so I won't go through
4 this. And then Dr.Kelley also talked a little bit
5 about the background. Under BRAC 2005, the Armed
6 Forces Institute of Pathology was directed to be
7 dis-established, except for several components,
8 one of them being the Tissue Repository, which is
9 germane to this conversation. Under the National
10 Defense Authorization Act of 2008, as Dr.Kelley
11 noted, I directed the President to establish a
12 Joint Pathology Center with four components.

13 One component is consultation, including
14 medical, dental, and veterinary services; the
15 second component is research; third component is
16 education, including graduate medical education
17 and continuing medical education; and the fourth
18 component is maintenance and modernization of the
19 Tissue Repository, which is currently owned by the
20 Armed Forces Institute of Pathology.

21 And, of course, at the Working Group,
22 eight courses of action, as Dr.Kelley noted, were

1 reviewed, carefully vetted, and the proposal was
2 for the one that was presented by the Joint Task
3 Force, CapMed. And so at that point then, we
4 started developing our Concept of Operations based
5 on what we had briefed -- we put in our course of
6 action for the Joint Pathology Center Working
7 Group.

8 The vision of the Joint Pathology Center
9 is to serve as the federal government's premier
10 pathology reference center supporting the Military
11 Health System and other federal agencies. The
12 mission is that the Joint Pathology Center will
13 provide world class diagnostic subspecialty
14 pathology consultation, education, training,
15 research, and maintenance and modernization of the
16 Tissue Repository in support of the mission of the
17 DOD and other federal agencies.

18 Under our Concept of Operations, as we
19 noted, the Joint Pathology Center will be under
20 the Joint Task Force, and it will actually be a
21 part of their premier medical center, the Walter
22 Reed National Military Medical Center. The Joint

1 Pathology Center will be under the -- for command
2 and control, be under the Department of Pathology
3 in Walter Reed National Military Medical Center.

4 This is our organizational structure
5 there. And you'll see that -- if you look at the
6 bottom there, you'll see that we actually cover
7 all the things that we require. Our diagnostic
8 service, which is in the middle there, is
9 basically our consultative service. The Tissue
10 Repositories we talked about. In addition, in
11 support of our Diagnostic Service, our Concept of
12 Operation includes standing up a state-of-the-art
13 Molecular Pathology Lab to support that Diagnostic
14 Service. Research and education, then, of course,
15 all the support pieces that go with that, are
16 noted on the right. And you'll see on the left,
17 there's actually two things which we'll touch on
18 very briefly. Under BRAC law, we're required to
19 stand up a Pathology Program Management Office,
20 and we'll talk a little bit about that shortly.

21 And then under BRAC law, we're required
22 to retain the -- it's the DOD Tumor Registry

1 System called ACTUR. And so we -- those will
2 actually be two things within the Joint Pathology
3 Center, as well.

4 The functions of the Joint Pathology
5 Center will be to provide subspecialty pathology
6 service, specifically subspecialty pathology
7 consultation to general pathologists within -- at
8 outlying medical treatment facilities. They'll
9 also support the Armed Forces Medical Examiner for
10 consultation, as well as the Centers of Excellence
11 within DOD.

12 And they'll do that by employing
13 state-of-the-art interpretative technology. As we
14 talked about, the Molecular Pathology Lab will
15 support that, as well as a robust
16 immunohistochemistry section, and
17 immunofluorescence section, as well. As we talked
18 about, under BRAC law, we're required to operate a
19 Pathology Program Management Office. And what
20 this office will do is, it will actually
21 administer and provide quality assurance oversight
22 for contracts for outside consultative services,

1 to basically provide outside consultative services
2 for anything that's beyond the scope of the Joint
3 Pathology Center.

4 We envision our Joint Pathology Center;
5 the way we have it proposed is that we should be
6 able to meet about 80 percent of the Department of
7 Defense's consultative needs in terms of
8 pathology. The other 20 percent or cases that are
9 just deemed too difficult for the Joint Pathology
10 Center will basically go out through the Program
11 Management Office to select world experts as
12 needed for consultation.

13 Under the NDA 2008, they actually
14 specifically state that we provide veterinary and
15 oral pathology consultative services, and, of
16 course, we've got that worked into our plan. Here
17 in the National Capital Region, there is a
18 Veterinary Pathology Residency Program within DOD,
19 as well as an Oral Pathology Residency Program,
20 and we're working with them to basically provide
21 the consultative services required under NDA 2008.

22 And as required under NDA 2008, the

1 Joint Pathology Center, under our proposal, we
2 will operate the world renowned Tissue Repository.
3 As most of you probably know, this is one of the
4 largest, most expansive tissue repositories in the
5 world, and we'll operate that with several
6 different facets. Number one, the Tissue
7 Repository will be used for -- to support our
8 pathology consultative service with prior case
9 material, you know, being able to compare it with
10 current ongoing cases.

11 We're also going to open it up to other
12 medical treatment facilities for clinical care, so
13 that they'll have opportunity to look at cases
14 that were submitted to the AFIP or to the Joint
15 Pathology Center and are now in the Repository.

16 If they're seeing a patient, for
17 example, at William Beaumont in El Paso, Texas,
18 and they need to see what the prior breast biopsy
19 or liver biopsy or whatever looked like, that
20 opportunity will be available.

21 In addition, I think equally as
22 important is that the Tissue Repository will --

1 there's so much material in here and so much
2 opportunity for utilizing that for research. Our
3 goal is to open that up and basically make that
4 material accessible for research within DOD and
5 the federal government. So that would be pretty
6 much the entire repository of archive tissue. The
7 Joint Pathology Center is a part of the new Walter
8 Reed National Military Medical Center. Since it's
9 a part of the Department of Pathology, it will be
10 an integral part of our Pathology Residency
11 Program at Walter Reed. So they'll provide
12 military medical education there. In addition,
13 it'll be a participating institution for the other
14 five DOD pathology programs and other federal
15 institution pathology programs, so that training
16 will be provided there.

17 In addition to graduate medical
18 education, we're looking at partnering with USUHS,
19 collaborating with USUHS to provide a robust
20 online continuing medical education program for
21 pathologists and other providers within the
22 federal government.

1 And we think that one of the
2 opportunities there is for us to provide
3 continuing medical education for our folks that
4 are deployed. We have physicians that are
5 deployed who don't have some of the opportunities
6 that we do state side for medical education.

7 And then we talked about the research
8 aspects, you know, the opportunity, especially
9 using the repository for research and opening that
10 up to the DOD and the other federal agencies for
11 research, so that's also one of the key functions
12 that we're looking at with the Joint Pathology
13 Center. Under our Concept of Operations, within
14 the Joint Task Force, we're looking at a personnel
15 requirement of 81 people, of which 79 of those
16 will be civilian, and in terms of pathologists,
17 that will be 25 total pathologists, of which 23
18 will be working within the consultative or
19 diagnostic service, and one position for the Chief
20 or the Director, and then a molecular pathologist
21 working in the Molecular Laboratory. The rest of
22 that is support.

1 Our work load here is based on the AFIP
2 work load for the last three years. So we
3 estimate that we would see about 24,000
4 consultative cases per year. In terms of facility
5 requirements, the majority of the Joint Pathology
6 Center would be housed at Forest Glen Annex, the
7 Forest Glen Campus up in Maryland. And actually,
8 that's a mistake on the slide, it's actually
9 54,500 square feet that we have up there that
10 currently houses the AFIP Tissue Repository and is
11 slated for renovation with MedCom dollars, Army
12 MedCom dollars, to support the Repository.

13 Looking at that, we feel that we'll be
14 able to easily fit in there our consultative
15 service, as well as our Molecular Pathology Lab,
16 in addition to the Repository that's there. The
17 administrative services, for example, the PMO
18 Office, as well as other admin support, will be on
19 the Bethesda Campus. Our equipment and initial
20 start-up costs, and this is a rough estimate,
21 about \$3 million, and this is above and beyond the
22 money that the Army Medical Command has slated for

1 renovation of the two buildings on the Forest Glen
2 Campus, so this is above and beyond that. And
3 like I said, this is a rough estimate which we'll
4 refine as we move on in this process.

5 Our estimated annual operating expenses
6 are about \$14.1 million. And once again, this
7 will be refined as we move on with the process and
8 see where we need to be at a later date.

9 Our key assumption is that this will be
10 program funding, it'll be through the Defense
11 Health Program. The VA currently provides
12 significant financial support to the AFIP, and one
13 of our key assumptions is that the VA will
14 continue this historical level of financial
15 support for the Joint Pathology Center.

16 And as good stewards of tax payer's
17 money, one of the things that we're looking at and
18 we're going to look at very, very closely is, what
19 equipment can we use from the AFIP. They have a
20 lot of good state-of-the-art equipment, especially
21 in the Molecular Lab and with all the microscopes
22 and everything, and we'll look at that all very

1 carefully and see what we can actually reuse. And
2 once again, as good stewards, we've been looking
3 very carefully at what efficiencies we can gain.
4 With this being under the Walter Reed National
5 Military Medical Center, we feel that there's
6 actually significant opportunity for us to
7 consolidate specific administrative services, that
8 is, histology services, transcription, and other
9 administrative services.

10 And at this point, we're actually
11 looking at at least a \$700,000 reduction in the
12 total cost of this as a result of these gained
13 efficiencies.

14 We also think that especially with the
15 repository material, we have an outstanding
16 opportunity to collaborate with other federal
17 agencies for research, and education, as well. So
18 we will be looking at that very, very closely.
19 But we feel this is one of our prime opportunities
20 with the Joint Pathology Center.

21 In terms of the way forward, as we move
22 through our careful vetting process of our Concept

1 of Operations, we will ultimately like to, of
2 course, gain approval of our Concept of Operations
3 and then develop an implementation plan. And this
4 implementation plan will be a very -- actually a
5 very detailed implementation plan with
6 implementation teams consisting of subject matter
7 experts, both at the AFIP and within DOD and
8 presumably other subject matter experts to look at
9 all the details that we need to do to this to make
10 sure that we do it right. That will be -- include
11 equipment, personnel that will be looking very
12 carefully at the Molecular Pathology Lab, the
13 Consultative Service, what do we really need, what
14 exactly do we need to provide, and so on.

15 So this is actually one of the key
16 points to our way forward, is to have a very good
17 implementation plan that covers all the issues
18 that we need to look at. And as we look at our
19 implementation plan, that will help us refine our
20 program requirements and really boil it down to
21 what is it that we actually need to do to do the
22 business of the Joint Pathology Center.

1 We will, of course, ensure strategic
2 communication with our stakeholders, the VA, the
3 AFIP, the medical treatment facilities that would
4 be using our services, USUHS, so all the
5 stakeholders, and we're actually already starting
6 that process.

7 Next, of course, we want to complete the
8 facility's renovation and finalize our equipment
9 acquisition strategy, keeping in mind that we're
10 looking at getting a lot of the equipment from the
11 AFIP if it meets our needs, so we're going to look
12 at that very carefully. And since there's 79
13 civilian positions within the Joint Pathology
14 Center, these positions will be filled under the
15 rules of the Civilian Personnel System within the
16 Joint Task Force CapMed. So whatever their
17 process is for that, this will be within that
18 process.

19 And, of course, we want to synchronize
20 the transition with Walter Reed as it closes the
21 old Walter Reed, as well as BRAC transition here
22 in the National Capital Region. And we want to

1 make sure that we stand up the Joint Pathology
2 Center, as the AFIP standing down, to ensure that
3 whatever services are going to -- at the AFIP that
4 we will also have at the Joint Pathology Center,
5 that we'll ensure that we'll be able to transition
6 these so that there's not a lull in consultative
7 services for the Department of Defense. What are
8 your questions?

9 DR. POLAND: I'm sure there will be
10 comments or questions that the Board has. Joe,
11 Dr.Parisi.

12 DR. PARISI: Thank you, Colonel Baker,
13 for your presentation. I only recently had an
14 opportunity to review the Powerpoint and your
15 Concept of Operations, so my comments are
16 relatively incomplete and preliminary at this
17 point. I thought it was very important for the
18 Defense Health Board to be reminded of the details
19 of the Defense Authorization Act of 2008 that
20 directed the President to establish the JPC, and I
21 asked Olivera to reproduce that, and you have a
22 copy of it here. And I think it recognizes -- I

1 think the law clearly directs that the JPC should
2 function as the reference center in pathology for
3 the federal government, so it's establishing a
4 very high bar here.

5 It also recognizes the enormous
6 contributions that the AFIP has made over the
7 years, which I think have been, to a large part,
8 under recognized, but it also suggests that maybe
9 the AFIP is a good model or at least a potential
10 model for this new Joint Pathology Center of
11 Excellence.

12 The law also provided, and I'm not sure
13 where we are with this, to be honest with you, but
14 it provided for the option of it not to be located
15 in DOD. And I think, having this Joint Pathology
16 Center or the reincarnated AFIP or something
17 similar to it in DOD is problematic, and I think
18 that's been a major thorn in the evolution of
19 AFIP. It seems to me that, historically, it made
20 sense to have it under Department of Defense when
21 it was established as a medical museum in 1862.
22 As the AFIP evolved, the functions became much

1 greater and much more complex, much more
2 collaboration without world, and it's taken on a
3 new flavor as it's become the -- as it was
4 recognized as the Center of Excellence for
5 Pathology throughout the world actually.

6 So I'm not sure it really belongs in the
7 Department of Defense. One of the problems with
8 having it under DOD is that it has to be
9 militarily relevant. And we heard that all the
10 time when I was on the staff, when I was a staff
11 person there, there was -- everything we do has to
12 be militarily relevant. Well, how do you define
13 that? If you define it medical care in the big
14 sense, then everything we do is medically
15 relevant. If you're talking about the field
16 soldier, then it's very limited.

17 And again, historically it made sense,
18 but the way pathology is practiced at the
19 Institute, and the variety of cases it's seen,
20 it's not necessarily exactly one to one militarily
21 relevant.

22 So because it's under Department of

1 Defense, it's historically under scrutiny by the
2 Surgeons Generals periodically, and they've always
3 looked for it to cut costs. If you look at the
4 big picture of things, and I was surprised
5 yesterday at the numbers we were presented with,
6 \$44 billion a year for health care, only six
7 percent of that goes to this subgroup that's
8 called, what was it called here, Consolidated
9 Health Support, six percent of the budget went to
10 Consolidated Health Support, and of that, less
11 than one-half of one percent funds the entire
12 AFIP. So I mean you're talking about peanuts here
13 in the big picture of things.

14 That's not to say you -- I mean we have
15 to be physically responsible, but this is a very
16 small number, and you're getting a lot of bang for
17 your dollar, I think here. So the money issue is
18 a problem, and I fully recognize that. On the
19 other hand, I think a function of our government,
20 and this is me talking, a function of the
21 government is to preserve things that are good for
22 mankind, good for science, good for society, and

1 good for the common good basically.

2 And it seems like we ought to be able to
3 find a place that would fund AFIP or fund this
4 Joint Pathology Center and make the bar very, very
5 high. I think -- I commend you for your plan, but
6 I think having it as a part of a medical center,
7 Department of Pathology, lessens its impact and
8 its stature. And I think there are some -- at
9 least philosophically, I think there are different
10 approaches that you might take to -- if you're
11 really serious about making this a Center of
12 Excellence, my feeling is it should really be a
13 free standing entity or attached to some other
14 federal agency, that's my take on it anyway.

15 And then I've got a whole bunch of
16 specifics that are more, you know, the devil is in
17 the details, and I've got a whole bunch of
18 detailed questions that I could ask, too, but
19 maybe other people would like to chime in at this
20 point.

21 DR. POLAND: Let me get Wayne, and then
22 Mike.

1 DR. LEDNAR: Wayne Lednar; as General
2 Kelley said, it's really been looked at that the
3 mission of AFIP can be done by DOD, if I heard you
4 correctly, sir, and, in fact, over the years has
5 been in DOD. So clearly we have a history of
6 performance that, you know, has been performed
7 within the structure of DOD.

8 I guess the question I have, and I'm
9 going to be sort of looking towards Ms. Embrey as
10 I ask this question, but as a federal government
11 premier resource, and that's bigger than DOD, and
12 we have the Tissue Repository, which is a unique
13 resource, and we have important health questions
14 that need to be addressed for DOD, this is a
15 research question, how do we take proposals to
16 utilize the Tissue Repository, for example, and
17 reconcile them against the entire DOD health
18 research agenda that this is a priority, it is
19 military relevant, it is a good and appropriate
20 use of this precious resource, and that there's
21 some rationalization before the Tissue Repository
22 begins to be depleted? I'm not sure who is the

1 best to respond to that.

2 COLONEL BAKER: Well, if I could answer
3 that, just a couple points here. We do need --
4 and the devil is in the details in how do we do
5 that and how do we do that, so that, you know, it
6 works properly and truly supports research within
7 DOD and the federal government.

8 As a part of a -- the fact that it's,
9 you know, it's now going to be a living
10 repository, meaning we're still going to have
11 active contribution and material to the
12 repository, I think one of our roles in the Joint
13 Pathology Center is to ensure that it doesn't get
14 depleted and that we reconstitute it with material
15 available from active consultative cases and
16 potentially other sources within DOD, including
17 tissue blocks before they get, you know, routinely
18 disposed at other places. I think we have a lot
19 of opportunity to ensure that we're not going to
20 just deplete the Tissue Repository, but that it'll
21 grow and actually be maintained as a vibrant
22 Tissue Repository for research purposes.

1 MS. EMBREY: And Joe Kelley may want to
2 add to this, but, you know, the fact that the
3 Center is being located in Bethesda, on the
4 Bethesda Campus right across from NIH is not
5 accidental. It is a rich resource, not only for
6 the military, but for the country, and it has a
7 history of -- its relationship with, you know,
8 this kind of research where it's needed. And
9 since it will be a Center of Excellence for
10 Pathology, it will be both military relevant, as
11 well as connected to the research that's going on
12 elsewhere. So I'm very confident that it's being
13 positioned in the right place.

14 DR. POLAND: Let me get Dr. Parkinson.
15 He was -- Joe, did --

16 DR. PARISI: Isn't it going to be at
17 Forest Glen? I thought that's what I just heard.

18 COLONEL BAKER: Yes, sir.

19 MS. EMBREY: Oh, I thought it was at --

20 COLONEL BAKER: Yeah, I'm sorry, it'll
21 be a part of the Walter Reed National Military
22 Medical Center, but the Tissue Repository is

1 currently up at Forest Glen and that's where it'll
2 remain and that's where the Consultative Service
3 and the Molecular Pathology Lab will be.

4 DR. PARISI: So it's going to be
5 physically separated from Bethesda is my point?

6 COLONEL BAKER: Well, it'll be
7 physically separated by a few miles, yes, sir.

8 DR. POLAND: Dr. Parkinson.

9 DR. PARKINSON: Yes, Mike Parkinson.
10 Well, again, just to -- maybe everybody else on
11 the Board understands this and I wasn't awake in
12 the first 15 minutes, but the statute, which did,
13 as Dr. Parisi mentioned, allow the possibility of
14 making this truly a federal agency, supporting the
15 federal government and other things nationally,
16 the 180 days has passed.

17 The Department has determined, i.e., the
18 President has determined that this will remain
19 within the Department. So, to me, the challenge
20 now is how to make it actually not only survive,
21 but thrive to meet the mission of what is in the
22 statute, which is to be a meaningful federal

1 agency to serve Americans, vice DOD with a tin cup
2 going around and hoping somebody reimburses you.
3 So the biggest direct care systems in this country
4 are the Veteran's Health Care System, you've got
5 some degree of money, and I guess it's not
6 specified how much that is, so the first question
7 is, is that adequate, and if not, how do we use
8 some strategy and tactics to increase the
9 reimbursement.

10 Number two is, obviously, although they
11 have less of a footprint, is the, you know, the
12 Public Health Service, which is AHECS and its
13 region, I mean its community health center
14 platforms, the Indian Health Service, where are
15 those subspecialty pathology dollars going now.

16 When I see a complex case at the Indian
17 Health Service in Santa Fe, and it goes to the
18 University of Mexico, those dollars have got to be
19 coming back. If there's a subspecialty,
20 hematology consultation, you should be having an
21 effected business model that makes it attractive
22 to send that FedEx or whatever you do to get to

1 AFIP, so start moving out. In other words, and I
2 think the leadership of the Department needs to
3 sit down with all of the other federal agencies
4 and say this is the premier center for
5 subspecialty consultation, 23,000 is not enough,
6 it should be 35, 45, 50, I don't know what it is,
7 but at a time when both presidential candidates
8 are talking about getting more money out of my tax
9 payer dollars, we need to start thinking a little
10 bit more like Quest Diagnostics, which says, no,
11 we have a competitive way to do this, and run the
12 risk of saying, well, the federal government
13 shouldn't be in trying to attract business.

14 I mean this is as much of an
15 opportunity. Now, it does mean that there's got
16 to be some heavy lifting even beyond the E-ring of
17 the Pentagon to say, what are we going to do to
18 make the government, when it does do special
19 services, that are not either volume intensity
20 enough such that Johns Hopkins can't do it or do
21 it as well as this place, how do we do that?

22 So I think there's a good news and bad

1 news story. I mean the historical ways that
2 Dr.Parisi of the AFIP and what it did, it truly is
3 at a time -- read the Wall Street Journal today,
4 what we're doing in advanced genomics and the
5 other ways we're trying to understand etiology of
6 cancers, I mean all the Tissue Repository, the
7 people you've got at AFIP have got to be part of
8 the national understanding, and without a robust
9 advanced pathology platform in the country, but
10 we've got to get out and market it, we've got to
11 have a strategic plan. I'd love for the DHP to
12 come back and say, okay, that's a great thing in
13 terms of bricks and mortar and budget in terms of
14 version 1.0, what is your strategy to get the VA,
15 IHS, PHS, FDA, you know, maybe it's already there,
16 maybe it's all that volume of effective work
17 that's come your way, but if not, what's the plan
18 to come back to DHB and make this thing a realty
19 so that there are people clamoring for your
20 services rather than being treated.

21 Unfortunately, it's kind of this, well,
22 it's not really relevant to Iraq today, which I

1 agree, it's not the right question.

2 DR. POLAND: Mike, and then Joe.

3 DR. OXMAN: I may also have been asleep
4 a little bit and may not have heard correctly, but
5 I think the independence of the Center is very
6 important, and it's very important that both
7 intellectually and budgetarily it isn't submerged
8 in an individual pathology department where it may
9 or may not prosper and may or may not lose its
10 identity. And so I'd like to hear about the
11 governance of the entity and how it will be
12 independent of the USUHS Pathology Department.

13 COLONEL BAKER: The Walter Reed
14 Pathology Department, it won't be a part of USUHS,
15 it'll actually be a part of the Walter Reed
16 National Military Medical Center, Department of
17 Pathology. It will be one of the services based
18 on our Concept of Operations, it will be one of
19 the services under the Department of Pathology,
20 but it'll be not only physically separate, but in
21 terms of pathology staff and what they do, they'll
22 also be functionally separate.

1 DR. OXMAN: Does that mean that there
2 will be any sort of independent board of overseers
3 who will be able to keep its independence and make
4 sure that it has broader representation than just
5 Walter Reed?

6 COLONEL BAKER: Well, I think that --
7 there's a lot of opportunity there to look at
8 that, I would agree with you. And one of the
9 things that we've talked about is, for example,
10 having a board made up, you know, of at least the
11 pathology consultants for the military services
12 and the VA. But there's probably opportunity to
13 look at that. And I agree, that's something that
14 we do need to look at.

15 DR. POLAND: Joe.

16 DR. SILVA: Joe Silva; just a technical
17 question. On these consultations --

18 COLONEL BAKER: Yes.

19 DR. SILVA: -- 24,000 per year, what
20 percent are outside DOD, and can you contrast that
21 say ten years ago with the AFIP? How much of a
22 subspecialty external DOD consultation do they

1 have now versus the past?

2 COLONEL BAKER: Well, sir, I can answer
3 about where these numbers came from. We actually
4 subtracted out the civilian consultations from
5 this, so this number does not include -- this is
6 DOD and the VA in terms of consultative material.
7 And Dr.Mullick can correct me if I'm wrong, but I
8 believe the civilian consults comprise about 33
9 percent -- 34 percent of the total work load. She
10 could probably comment on that a lot better than I
11 could.

12 DR. MULLICK: The evidence work load for
13 civilian, military, and VA has been around 50,000,
14 up and down a little bit. In the last couple of
15 years, because of the BRAC and the feeling that
16 AFIP cannot do the consults because they are
17 winding down and people are leaving -- which is
18 incorrect, the consults have gone down. It has to
19 remain at 34 or 35,000. So the number that
20 Dr.Baker calculated is eliminating all the
21 civilian consultations and I guess other related
22 agencies and giving -- presenting only the

1 military and the smaller percentage of VA cases.

2 DR. POLAND: We need to wrap up in a
3 minute or two here. But Wayne and then Joe, I
4 mean Russ, sorry.

5 DR. LEDNAR: Wayne Lednar; I realize as
6 part of BRAC, there's clearly some expectations,
7 call it institutional blocking and tackling, but I
8 have an operational question, and that is, how
9 this move, how this change is better, better for
10 DOD, better for the federal government, and can
11 you share with us how those who are served by the
12 AFIP and these 35 to 50,000 consultations per
13 year, what their sense was as you developed this
14 Concept of Operations, and then as you put
15 together this plan, how this addresses some of
16 those concerns from those the Military Health
17 System request in particular?

18 COLONEL BAKER: Yes, sir, I can actually
19 comment on the Military Health System, the
20 concerns of the Military Health System. Losing
21 the -- the AFIP provides, you know, a lot of great
22 services for the Military Health System. And as a

1 general surgical pathologist, you know, I still
2 practice, the AFIP provided invaluable
3 consultation during my 20 years, and that's one of
4 the biggest things that we lost, with the AFIP
5 going away under BRAC.

6 The process that was put into place with
7 the AFIP and being dis-established, the Program
8 Management Office process of basically sending out
9 consultations to whatever consultants had
10 contracts we saw as potentially problematic in
11 that we did not -- we benefit from one stop
12 shopping, knowing that our cases, you know,
13 especially the military relevant ones, they're
14 going to be seen by ID, by -- by, you know, so on
15 and so on, so that was one of the things that we
16 feared losing with going with, you know, basically
17 sending out all of our cases.

18 And I think with, you know, looking at
19 the key components of the NDA 2008, and our Joint
20 Pathology Concept of Operations, we're going to be
21 able to bring a large part of that consultation
22 back into DOD, ensure that it's one stop shopping,

1 ensure that we're able to track military relevant
2 things, you know, such as, you know, if there's
3 any, you know, new infectious disease, things like
4 that, you know, that come out of that, we'll have
5 that opportunity to do that as a one stop shop.
6 So I think from a consultative standpoint, this
7 will greatly benefit, significantly benefit the
8 DOD and the VA.

9 DR. POLAND: Dr.Luepker, do you want to
10 make a comment?

11 DR. LUEPKER: Yes, Russell Luepker, two
12 quick questions about money directly and
13 indirectly. BRAC, as I understood it, was a cost
14 -- partly driven by cost saving issues. I'm
15 curious how this new plan plays out in terms of
16 overall costs or cost savings. The second, and
17 I'm not sure I tracked the whole thing here, but
18 there's discussion about -- it sounds like fee for
19 service in the rest of the world, in the
20 non-governmental world, and having done some of
21 that as a government agency, it's tricky business,
22 and one -- one needs a business plan to do this,

1 and maybe you're doing it already and making money
2 hand over fist, but if you're not, you ought to
3 think about it a lot.

4 COLONEL BAKER: I'm sorry, sir, I was
5 concentrating on your last question there.

6 DR. LUEPKER: How is this going to save
7 money under BRAC?

8 COLONEL BAKER: Yes, sir, sorry about
9 that. Well, a couple things; I mean when we put
10 together our plan, we were looking at, number one,
11 what were some of the funding that was already out
12 there as a result of BRAC. For example, our
13 Pathology Management Office process is slated for
14 somewhere in the neighborhood about \$7 million.
15 The VA contributes a portion. The Repository,
16 since it is required to be maintained under
17 modernized -- maintained and modernized under BRAC
18 law, there's money that goes with that. So right
19 there, there's about \$12 billion plus that are
20 going for -- that are already there to provide
21 those services that we're going to basically be --
22 maintain after BRAC. So, you know, I think in

1 terms of looking at the total cost, you have to
2 kind of look at the fact that there's \$12 million
3 right there that was already kind of slotted to
4 provide those services. So now we're looking at
5 the quality of the care that we're bringing back
6 in, which is that one stop shop, you know, having,
7 you know, cases being able to be looked at by
8 infectious disease, hematology, by GI or whatever
9 in the course of getting an appropriate consult
10 that really serves our needs.

11 DR. KELLEY: If I might add just a
12 little bit on that.

13 DR. POLAND: Briefly.

14 DR. KELLEY: I think there's three
15 pieces, we just mentioned one, for the funding.
16 The PMO was also included in the BRAC law, so it
17 was funded before. And then the BRAC law assumed
18 that all of the consults would be going down to
19 the civilian community and would have to be paid
20 for, and the ones that are brought back, that
21 funding is there, too. So there's three pieces of
22 funding. The question about in DOD, as

1 Dr.Parkinson said, that decision has been made,
2 that it could be, it was directed to be done in
3 DOD unless it could not be done in DOD, and the
4 decision was made that it could be. This is a way
5 it could be done, so therefore, it could be done,
6 and it will be done in DOD. And --

7 DR. POLAND: Okay.

8 DR. KELLEY: -- one other aspect of law
9 that hasn't been mentioned is that it has to
10 follow the BRAC law, and so we can't ignore
11 anything that's directed in the BRAC law, and
12 that's both in the BRAC law and in the NDA that
13 establishes the Joint Pathology Center.

14 DR. POLAND: Thank you for that
15 clarification. Let me wrap things up here. The
16 JPC issue, as I see it, involves technical aspects
17 associated with the pathology services, issues
18 associated with establishing a Center of
19 Excellence in the NCR, and issues associated with
20 health care delivery as they relate to the support
21 of the Military Health System and DOD.

22 As a way to deal with this, what I would

1 like is Representation of the Health Care Delivery
2 Subcommittee, the NCR BRAC Advisory Panel, and the
3 Scientific Advisory Board for Pathology and
4 Laboratory Services, all parts of our group, to
5 review that plan. In specific, Dr.Parisi I think
6 could take the lead on that, and other members of
7 the Pathology Group should also participate, since
8 the input of those individuals I think is key.
9 Since it will involve the NCR, I hope Dr.Kizer,
10 Mr. DuBois, and Dr.Carlton would also be involved.
11 And from a Health Delivery standpoint, I'd like
12 General Anderson, Dr.Kokulis, and Dr. Lednar to be
13 a part of the group.

14 The Department needs to have an answer,
15 as I understand it, by October, so I think a way
16 forward here is one to review the written plan,
17 now that we have it. Joe, for your group and the
18 group of individuals I mentioned, to independently
19 develop questions and comments that you would have
20 about that, and if you can, to meet as a group
21 within the next ten days, given the timeline that
22 we have, within the next couple of weeks, and

1 expect the DOD Work Group members to be available
2 to discuss specifics of it; does that sound
3 acceptable, Joe?

4 DR. KELLEY: We'll certainly work on it.

5 DR. PARISI: Maybe we can do it by phone
6 conference, at least --

7 DR. POLAND: Yeah, I think you may well
8 to facilitate it. Go ahead.

9 DR. PARISI: But I think there are
10 several issues that we need to talk about.

11 DR. POLAND: Yeah, you need to dig into.
12 Okay, thanks.

13 DR. PARISI: So just -- it is part of
14 the -- that's a closed issue, and it's -- go
15 anywhere else.

16 DR. POLAND: Dr.Kelley, is that correct?

17 DR. KELLEY: I think that's correct. I
18 do not foresee it going anywhere else. I mean the
19 -- I think that the decision has been made.

20 DR. POLAND: Okay.

21 DR. MULLICK: Can I ask just quickly; I
22 think it was -- I don't think it was Dr.Parisi,

1 but somebody mentioned that the President had
2 approved this JPC and DOD -- I was not aware of
3 that. Has it gone to the President and been
4 approved by the President? I thought I heard -- I
5 think Dr.--

6 DR. POLAND: He didn't return my call,
7 so I --

8 DR. PARKINSON: No, that was just a turn
9 of phrase, because when the Department, acting on
10 behalf of the President, as in the statute, so I
11 think the Department, from General Kelley, has
12 said we can't make a compelling argument, nor
13 should we make a compelling argument based on the
14 Department's decision, i.e., quotes the President,
15 I mean that's all.

16 DR. MULLICK: Oh, okay.

17 DR. PARKINSON: I was just --

18 DR. MULLICK: I've been following it.

19 DR. PARKINSON: I'm sure it didn't go to
20 the White House.

21 DR. MULLICK: Following closely then the
22 process, and I remember all of Dr.Kelley's

1 documents, each one of them, and there is a series
2 of things, you know, and I didn't think the
3 President had been in the loop yet, but --

4 DR. POLAND: Okay. Thank you very much.
5 I think we need to move on.

6 DR. PARKINSON: Okay. Thank you, sir.

7 COLONEL GIBSON: The Defense Health
8 Board staff will support you as far as a physical
9 meeting as soon as we possibly can and any
10 teleconferences that you want to put together.

11 DR. POLAND: Okay. We've got two new
12 questions to come before the Board, one regarding
13 Chronic -- Syndrome and the other on autism and
14 applied behavioral analysis therapy. After we
15 work through these questions, there will be an
16 opportunity for anyone who wants to to make a
17 public statement. In order to do that, if you
18 have not done so, register on the sign-in sheet
19 with Lisa Jarrett right outside the room. Written
20 statements are also welcome and will be reviewed
21 by the Board. So the next speaker then is Deputy
22 Assistant Secretary of Defense for Clinical

1 Programs and Policy, Dr. Joseph Kelley, who will
2 provide an update regarding a question that was
3 recently brought to the Board concerning the use
4 of therapy for Lyme Disease. You can find the
5 presentation slides, as well as a copy of the
6 question under Tab 10 in your notebook. And we
7 have set aside 15 minutes for this on the agenda.
8 Dr. Kelley.

9 DR. KELLEY: And what I think I'll do,
10 sir, is that, I will just introduce it, and if you
11 could push the first slide. There have been a
12 large number -- a small number of prominent cases
13 of Lyme Disease, and there has been some
14 discussion, there's been some discussion in the
15 open press about the appropriate diagnosis and the
16 appropriate treatment both for acute, but more
17 discussion in terms of chronic Lyme Disease, in
18 making the diagnosis, and how that should be in.

19 We would like to ask the Board to review
20 the diagnosis and treatment of Lyme Disease and
21 provide us some advice on how that should be
22 implemented in DOD. And I think that we can --

1 you have the slides that I put out, and I think we
2 have a follow-on presentation, which I think we
3 should just go to right away.

4 DR. POLAND: Thank you. Then we'll move
5 right on to Lieutenant Commander Todd Gleeson from
6 the Infectious Disease Department of the National
7 Naval Medical Center, who will brief the Board on
8 clinical issues regarding Lyme Disease within DOD.
9 His presentation is also under Tab 10.

10 DR. GLEESON: I appreciate everyone's
11 time for this important topic, and I appreciate
12 representation from ILADS, as well. So recently
13 there have been some issues, some key issues
14 raised in the diagnosis and management of Lyme
15 Disease, and I think the main issues are in the
16 diagnosis of infection with *Borrelia burgdorferi*.
17 There is incomplete, not 100 percent sensitivity
18 of the screening test, and so the main argument,
19 main concern of most people is, are we missing
20 cases, are we missing the diagnosis in our
21 patients.

22 And then recently the Attorney General

1 of Connecticut brought up a lawsuit against the
2 IDSA, Infectious Diseases Society of America,
3 stating that their guidelines then withheld by
4 preventing insurance payments, withheld needed
5 therapy from a lot of patients with the diagnosis
6 of Chronic Lyme Disease, and that's still an
7 ongoing process. In general, there are two camps
8 of thought, IDSA versus ILADS, International Lyme
9 and Associated Diseases Society guidelines.

10 The reason that I'm presenting is just
11 to provide information on how we, Infectious
12 Diseases military physicians, diagnose and
13 management Lyme Disease. Some background; there
14 are multiple diagnostic methods that we use.
15 First of all, with the erythema migrans rash,
16 which I'll show you, that's diagnostic in and of
17 itself. We do not recommend confirmatory testing
18 with blood testing later, we diagnose and we just
19 treat.

20 Currently the CDC and the IDSA recommend
21 a two tier testing system where we do a screening
22 ELISA to detect antibody, but then a confirmatory

1 western blot if that ELISA is positive or not
2 completely negative. There are other tests that
3 we have, there's PCR, which we can do PCR on the
4 blood in patients, and up to 65 percent of
5 patients with multiple EM rash, they'll have a
6 positive PCR. And in patients with a single EM
7 rash, 45 percent of those patients will have a
8 positive PCR in blood. And we also do multiple
9 lumbar punctures in our patients and look for Lyme
10 involvement of the CNS. And we really have a
11 large training component. For example, I just
12 went down to Pax River, Branch Medical Clinic in
13 the Navy, and gave a Lyme update and tick borne
14 diseases talk, and this is what I teach at the
15 National Naval Medical Center, and Walter Reed, as
16 well.

17 In the New England Journal article -- of
18 Internal Medicine, you'll see that it's not that
19 always classic target rash, it's, in fact, 59
20 percent of presenting Lyme Disease with rash, you
21 have a homogenous erythema, and then you might
22 have central erythema, and the classic bulls eye

1 rash is only seen in nine percent of patients, and
2 this is where one potential miss of Lyme Disease
3 patients occurs, it's misdiagnosed as cellulites
4 and not treated with Doxycycline. But with
5 education, and with seeing these patients back, we
6 do get the diagnosis.

7 So the two tier testing, screening with
8 the ELISA is insensitive in the first two weeks of
9 infection. By four weeks of infection,
10 sensitivity is maximized. And again, if it's
11 positive or indeterment, I would do a western blot
12 for both IGM and IGG, and we use CDC criteria for
13 interpretation. We use only FDA approved testing
14 at the National Naval Medical Center. We do use
15 an ELISA that we do in-house, and we sent our
16 western blots out to Quest. And at Walter Reed
17 they use a different ELISA in-house. They also do
18 their western blots in-house. The sensitivity and
19 specificity of our screening tests are about the
20 same. They, at their max performance, it's 86
21 percent sensitive, but remember, that's not 100
22 percent, which drives a lot of the argument here.

1 A lot of providers in D.C., where our
2 patients go if they're unhappy with MTF care and
3 they want a second opinion, and I've spoken to at
4 least three of these physicians in the area,
5 National Integrated Health is one clinic, and they
6 often send their tests to IGenEX in San Antonio,
7 I'm sorry, Palo Alto, California, I've spoken to
8 that lab, as well. They're not FDA approved, and
9 they say that they do not need to go after FDA
10 approval, they have internal validation assays
11 only.

12 But what's really important is that when
13 I see these patients eight months into their care
14 by providers in the D.C. area who claim Lyme
15 specialty, they've been paying out of pocket, not
16 for the pharmaceuticals. They can take a paper
17 prescription to our pharmacies and get that
18 filled. It's mostly in paying for the lab
19 testing, as well as the provider visits. It
20 drives the Lyme wars. And this is -- by the
21 previous President of ILADS, in that, since we
22 have such miserable sensitivity of our testing,

1 which he claims 56 percent, we're missing a lot of
2 patients, and they go across our desk without
3 getting a diagnosis. Really, in the first two
4 weeks, certainly the sensitivity can be that poor.
5 It's improved to 81 to 86 percent by three to four
6 weeks.

7 This is what we use at NNMCC, and you'll
8 see that in this study they used positive sera
9 early -- in early convalescent disease and then
10 early neurologic disease. And the sensitivity is
11 on the right, and you'll see that the best it does
12 is 81 percent.

13 You know, we won't hide the fact that
14 our screening test is not 100 percent sensitive,
15 as we want in a screening test. We'll talk about
16 that in a bit.

17 Treatment durations for Lyme Disease,
18 that is on behalf of the Infectious Diseases
19 Society of America, in terms of their guidelines,
20 I'm not a representative specifically, but I am a
21 member of IDSA, the treatment durations are well
22 studied, and we in the military ID, Internal

1 Medicine, Family Practice, generally follow these
2 guidelines, but it is our choice. The ILADS
3 guidelines are discussed frequently in our ID
4 conferences, and we necessarily need to know what
5 those guidelines are, because our patients that
6 come to us generally give us a copy of those
7 guidelines, as well as other web sites. These are
8 the guidelines we use, and again, these are under
9 re- review. Presently, in May, 2008, the Attorney
10 General of Connecticut made a statement that the
11 outcome of their lawsuit is that there will be,
12 without conflicts, a board to review these
13 guidelines in terms of the evidence.

14 Corroborating kind of the IDSA
15 guidelines, but I will admit that there was one
16 member of the IDSA Board on this Board of the
17 American Academy of Neurology Review of treating
18 Lyme in the central nervous system. In Europe,
19 for example, Doxycycline alone for ten days -- 14
20 days, is adequate for treating CNS disease.

21 However, in North America, we only have
22 Burgdorferi borrelia, they have many other species

1 over there, so it's not exactly commensurate data.

2 However, the American Academy of
3 Neurology also feel that for treatment of central
4 nervous system disease, 28 days of intravenous
5 Ceftriaxone is adequate, and even 14, 21, or 28
6 days, but beyond that is not needed. And this is
7 what we generally use. There are many different
8 stages of Lyme Disease, where if we, for example,
9 have a tick bite, we can give one dose of 200
10 milligrams of Doxycycline if it's an Ixodes tick
11 within 72 hours, and within at least 36 hours of
12 attachment. But if you have erythema migrans, you
13 can give 14 days of therapy with Doxycycline, for
14 example, or Amoxicillin. And then if you have
15 more invasive advanced disease, the regimens
16 generally become IV and longer, up to 28 days.

17 And again, we do -- and we are
18 conversant with the ILADS guidelines, both in ID,
19 as well as in internal medicine at Bethesda and
20 Walter Reed. In general, if you look at Lyme
21 Disease patients, up to 13 percent of them in well
22 designed prospective studies will develop a

1 symptom complex of fatigue, difficulty
2 concentrating, aches, pains, headaches. This is
3 defined by this group mostly as a chronic Lyme
4 Disease diagnosis, and they postulate that this is
5 due to ongoing infection, relapsed infection,
6 refractory infection.

7 The IDSA standpoint is that there are no
8 viable borrelia organisms left in the body and
9 it's not a persistent infection, which does not
10 require more antibiotics. And the statement then
11 is, there is a post- Lyme Disease syndrome in the
12 IDSA guidelines explained where the symptoms, if
13 they -- if the duration is greater than six months
14 after your Lyme Disease diagnosis, then you have a
15 diagnosis of post-Lyme Disease syndrome.
16 Recently, and I actually give a copy of this
17 article in the New England Journal to my patients
18 when I see them in consult usually well into this
19 process, there's a critical appraisal of chronic
20 Lyme Disease, and again, these authors redefine
21 and say there's a post-Lyme Disease syndrome for
22 sure, but there's not chronic infection that

1 requires more antibiotics.

2 I just picked two cases that I saw in
3 clinic, and we see this very frequently, I see
4 about two patients per week in consultation for
5 Lyme or chronic Lyme Disease. This was a 35 year
6 old pilot, came to me with fatigue, difficulty
7 concentrating, and headaches three times per week
8 responsive to Tylenol. His Lyme ELISA was
9 negative at Pax River. But recently his daughter,
10 two years old, was recently hospitalized for Lyme
11 arthritis and had a definite diagnosis by blood
12 tests, and this was a major stressor.

13 He took his whole family to our MTF and
14 felt that he was blown off, and then wanted
15 further evaluation with the National Integrated
16 Health. Also went to a Lyme specialist in
17 Connecticut, drove his whole family up there. At
18 Bethesda, our two tier testing was negative. In
19 fact, I sent a western blot despite a negative
20 screening test, and that was also negative. And
21 the provider at NIH, the other NIH, sent blood to
22 IGenex, and that was indeterminate. But he wrote

1 prescriptions and set a peer trial therapy to see
2 if his symptoms get better. And so by the time I
3 saw him, he had had over eight months of
4 Amoxicillin and Azithromycin, which was filled at
5 our pharmacies.

6 This just puts, in my opinion, the
7 patient at risk for selection of organisms such as
8 Strepneumo, as well as C-Dif infection, Claust --
9 infection, certainly in this age of Super C-Dif,
10 as well. And we have a lot of data on chronic
11 Azithromycin usually into a lot of resistance, for
12 example, in our H-pleurigastritus.

13 Clinical case two, I use this to show
14 that we are not draconian with the IDSA
15 guidelines. This was a 41 year old male, active
16 duty, '05, in the Army, had a tick bite a long
17 time ago, in 2004, was given empiric therapy for
18 two weeks, never had a rash. He was evaluated by
19 a neurology in December, '04; his Lyme testing was
20 negative, including his CSF testing, and they
21 still gave him some Doxycycline for 30 days.

22 In 2006, his Lyme serologies were again

1 negative. He saw the civilian provider in
2 Fairfax, Virginia, who sent IGeneX testing to
3 California, which was positive, recommended six
4 months or more of IV Ceftriaxone with symptom
5 scores monthly to see if the symptoms were getting
6 better as the objective end point. Saw Walter
7 Reed, repeatedly negative testing, however, we
8 said it's not unreasonable to give intravenous
9 Ceftriaxone to this patient, we have not yet
10 explained his neurologic symptoms, and his
11 antibody response back in 2004 may have been
12 abrogated by the Doxycycline that he was given,
13 which is a true statement. But beyond that, 28
14 days is not substantiated by the literature. So
15 he did get that therapy and was still upset with
16 not getting more than a month of Ceftriaxone.

17 So up to 25 percent of patients will
18 experience fatigue or muscle aches after
19 antibiotics, and over time, most of them do return
20 to normal. But if you have persistent symptoms
21 beyond six months, this is where a post-Lyme
22 Disease syndrome, in our opinion, is the

1 diagnosis.

2 So up to 13 percent in well designed
3 prospective studies will have subjective symptoms
4 of unknown cause. Fatigue and headache is part of
5 that. In some studies, these symptoms occur in
6 the general population, up to ten percent. So
7 it's not known if there is specifically an
8 increased risk of these symptoms after Lyme
9 Disease. Most of these studies never had a
10 control group to show whether this was higher than
11 the general population or not. And most of our
12 position on prolonged IV or pelotherapy is
13 unreasonable.

14 It was in 2001, in the New England
15 Journal, and they had 78 patients who were
16 positive for Lyme Disease on testing, 51 patients
17 who are negative on testing, they all had at least
18 some objective data of having maybe the EM rash of
19 Lyme Disease or other objective data, which a
20 physician said that they probably had Lyme
21 Disease, and they were given either one month of
22 IV Ceftriaxone with two months of oral

1 Doxycycline, or they actually got a pic line,
2 identical appearing intravenous and then oral
3 placebos.

4 And in general, they found no
5 significant differences in the scores between
6 those who got those antibiotics and those who got
7 the placebo. So there does not seem to be a
8 positive effect, a durable effect of antibiotic
9 therapy in these patients with this diagnosis of
10 post-Lyme Disease syndrome. So our policy
11 recommendations are to continue to use the IDSA
12 guidelines. We are waiting as a community, as ID
13 community, for this re-review of the guidelines
14 based on the lawsuit by the Attorney General of
15 Connecticut, and I think a lot of information will
16 come at that point. I don't know the date that
17 that will come about, but I expect it within the
18 calendar year.

19 So in conclusion, although the
20 sensitivity of our tests are not 100 percent, we
21 use more data than just that test. And we also
22 teach that, look, our sensitivity of our testing

1 is, at best, 81 percent. So we do treat patients
2 empirically if we think that they were exposed and
3 they have a symptom complex of Lyme Disease.

4 We ID specialists and the MTF's are
5 available 24 hours a day for consultation, and we
6 do consults on many, many of these patients. And
7 in our opinion, we think the ILADS guidelines,
8 which recommend prolonged antibiotics, often IV
9 with its associated problems, and potential
10 iatrogenic harm to our patients, is not what we
11 endorse at the present time. Any questions?

12 DR. POLAND: We'll make a few comments
13 here. The plan will be, of course, for the
14 Infectious Diseases Control Subcommittee to dig
15 into this. I would like to ask the help of a few
16 additional people based on their expertise in
17 this; one is Dr.Parisi, because of his expertise
18 in neuropathology, Dr.Reddick, and General
19 Anderson. And what we'll do is meet, come up with
20 our recommendations, and bring those back to the
21 Board for vetting, so that would be the process.
22 Questions or comments, though? Ed.

1 DR. KAPLAN: Kaplan; could you tell me,
2 maybe I missed it, the burden of disease?

3 DR. GLEESON: So I think recently, a
4 look at the data for the past 365 days was 3,700
5 cases of Lyme Disease diagnosed and treated and
6 MTF's in Army, Navy, and Air Force.

7 DR. KAPLAN: -- annually?

8 DR. GLEESON: Annually, yes, sir.

9 DR. POLAND: Dr.Oxman.

10 DR. OXMAN: Dr.Oxman; I'd just like to
11 make a comment, and maybe it's, again, my slow
12 hearing this morning, but prolonged IV antibiotic
13 therapy, in addition to the risk of selecting for
14 resistant organisms and colitis, there's an
15 enormous risk of super infection with
16 staphylococcal endocarditis, and so I think that
17 in the absence of good justification, the use of
18 long term IV antibiotics is something that we
19 should consider as an additional risk, and a risk
20 of potentially fatal complications.

21 DR. POLAND: Dr.Miller.

22 DR. MILLER: I always like the term

1 idiopathic, where the patient has pathology, and
2 the DR.s are usually idiots in not knowing what's
3 going on. And in this particular case, there's a
4 lot of other controversies, and medicine is --
5 what is the diagnosis in the end, and what do
6 these patients actually have. What is the gold
7 standard actually that's being used in terms of
8 defining the sensitivity and specificity of these
9 tests?

10 DR. GLEESON: Yes, sir; so these are not
11 only erythema migrans positive patients, but
12 Borrelia burgdorferi cultured from these patients,
13 either from the EM rash or blood.

14 DR. MILLER: So the culture results are
15 that high, higher than the other confirmatory
16 tests?

17 DR. GLEESON: Well, what they have done
18 is, they've taken those patients that they're able
19 to culture Borrelia from, and truly PCR is more
20 sensitive, so if you have an EM rash, single EM
21 rash, you can get PCR from the blood, detect its
22 DNA in 45 percent. If you have multiple EM rashes

1 from the spirochetemia, you can see it in 65
2 percent. But the cultures are probably 20 percent
3 lower than PCR in terms of growing it. So once we
4 get a subset of patients from which we actually
5 grew *Borrelia*, then we actually run our serologic
6 assays on those patients or use that as the gold
7 standard.

8 DR. POLAND: Dr.Gardner.

9 DR. GARDNER: Pierce Gardner; yeah, but
10 in your slide, you showed that only nine percent
11 of what you're regarding as a rash, I think that
12 you were including -- actually had classic EM. So
13 presumably that's your -- that should be your gold
14 standard, because the others have other set of
15 possibilities that will cloud the issue.

16 And it's the fundamental issue, of
17 course, that the epidemiologists would like to
18 make a tight diagnosis that they could account the
19 real, real, real cases, and the clinician faced
20 with patients with wide symptoms would like to fit
21 as much as they possibly could into a diagnosis of
22 Lyme Disease, and until there really is a gold

1 standard test that one can really rely on, and we
2 haven't ever got there, it's going to become a
3 clinical opinion in which I had to write an
4 editorial about this, I said uncertainty breeds
5 strong despaired opinions, and that will, in fact,
6 it'll be a who shouts the loudest and gets the
7 most attention until we can actually find the gold
8 standard to us, and we are -- we haven't made much
9 progress in the last few years.

10 DR. POLAND: Dr.Walker.

11 DR. WALKER: The serologic tests may
12 have better sensitivity than we believe. There
13 are patients with erythema migrans, particularly
14 in the Southern United States, that are associated
15 with the -- bites that do not transmit Borrelia
16 burgdorferi. So there are patients you can see
17 are erythema migrans, and it's really -- it
18 doesn't indicate that the Lyme Disease serology is
19 incorrect.

20 And I'll also tell you that -- because
21 I'm an expert in a couple of other infectious
22 diseases, like Rocky Mountain Spotted Fever and --

1 infections, I am approached almost every week by
2 patients who claim to have chronic Rocky Mountain
3 Spotted Fever and chronic humanmonisiactripiosis,
4 neither of which has got any evidence for there
5 being a chronic form of the disease.

6 DR. POLAND: Okay, thank you. Okay. We
7 have opportunity now for open discussion and
8 comments from the audience. Ms. Jarrett will
9 assist us in having members of the public who have
10 registered. Do we have any, Lisa?

11 MS. JARRETT: Yes; we have two public
12 comments regarding the Lyme Disease.

13 DR. POLAND: Okay. Sorry, go ahead.

14 MS. JARRETT: The first one being
15 Dr.Daniel Cameron.

16 DR. POLAND: Okay. Dr.Cameron, are you
17 -- please take the microphone. I'll ask each of
18 you to please keep your statement under five
19 minutes, if you can, so that we can get through
20 all that we have to do. And, Dr.Cameron, could
21 you just introduce yourself again, please, for the
22 Board?

1 DR. CAMERON: Okay. I'm Dr. Daniel
2 Cameron, I have been in private practice in Mt.
3 Kisco, New York since the late '80's. And to
4 speak at this body where evidenced based medicine
5 is such a premium, I was heartened when Dr. Steer
6 described neurologic Lyme as memory and
7 concentration problems, irritability, sleep
8 disturbance in 1990, and Dr. Fallon described all
9 kinds of emotional issues that were originally
10 diagnosed as psychiatric disease.

11 There were several publications in the
12 early '90's. What was -- what I found, since I'm
13 an internist in primary care, is that I was
14 disappointed when the IDSA took an evidenced based
15 medicine approach, put a panel of 12 people
16 together in 2000, and concluded that there was no
17 such thing as chronic Lyme as a distinct
18 diagnostic entity. So it doesn't fit very well
19 with my practice and the patients, and so I put
20 together a panel that looked at the evidence and
21 published that evidenced based guidelines,
22 reaching significantly different conclusions.

1 And so in the packet that I have before
2 you, I wanted to at least have it in a folder,
3 those guidelines, so that a good read between what
4 that ILADS panel came up with and what you read on
5 IDSA is appropriate.

6 What happened next is that in 2006, the
7 IDSA came up with another panel, it came up with
8 much more of an elaboration on this whole chronic
9 Lyme, post-Lyme Disease syndrome type thing, and
10 so in my comments under the issue and discussion
11 is that there were three conclusions that were so
12 different between the IDSA and ILADS.

13 One is that chronic Lyme Disease does
14 not exist. And so there are very few real good
15 epidemiology studies. I'm an epidemiologist at
16 the master's level from the University of
17 Minnesota, so I dusted off my degree from the
18 '70's, looked at the data, and the surveillance
19 definition for the CDC doesn't look for chronic
20 Lyme or post-Lyme, so there's very few numbers as
21 to how many people are sick. The slide you saw
22 earlier with about ten percent -- 13 percent

1 treatment failure, that was of EM rashes, where
2 they meet entrance criteria, they're identified,
3 they're treated decisively in a clinical trial.
4 But if you do a nice case control or cohort study,
5 you find that 34 to 62 percent of people are sick
6 on long term follow-up, so there were 34 percent
7 sick in a Massachusetts cohort with arthritis,
8 recurrent -- neurocognitive impairment, and
9 neuropathy, and 62 percent of a cohort in
10 Westchester County, this was 3.2 years later. So
11 one was six, one was 3.2 years, showing that on
12 long term follow-up, these people are sick.

13 Also, the Klempner Study, even though
14 they don't talk about it, they were sick for an
15 average of 4.7 years before they even got in the
16 study. So you're dealing with a particularly sick
17 population. Even Dr. Fallon's study at Columbia,
18 they were sick for nine years on average before
19 they got in that study. So it shows at least
20 there are people out there sick.

21 The second difference is that Lyme
22 Disease is nothing more than aches and pains of

1 daily living, which was talked about at the slide
2 earlier, that there are people with aches and
3 pains. But if you look at -- and there's a paper
4 in here that's published, 22 different independent
5 carefully designed measures, from the short term,
6 36, the fatigue severity scale, the fibromyalgia
7 severity scale, all of them show they're as bad as
8 fibromyalgic chronic fatigue patients, worse than
9 diabetes, worse than heart attack, and every one
10 of those measures in there shows that these people
11 are severe, they're far from the normal aches and
12 pains of daily living.

13 So that doesn't mean I always have the
14 right answer for how to treat in my practice, but
15 at least they're sick.

16 Also, there's an economic study that
17 showed that these people were costing 16,199 a
18 year, and 95 percent of that were not the DR.s,
19 there were indirect costs and non- medical costs
20 and productivity costs.

21 And the third difference is that there's
22 no credible evidence that antibiotic treatment is

1 effective. If you look at the actual trials, the
2 four NIH sponsored trials, the biggest problem is,
3 they were sick for 4.7 years in the Klempner
4 Study, nine in Fallon, and with that type of data
5 base, that's like a post traumatic stress disorder
6 patient, they're often much more difficult to
7 treat than one therapeutic modality, and we're
8 finding in ILADS those cases that got talked about
9 on these slides earlier are going to take more
10 than an antibiotic, they're going to take some
11 dietary changes, some counseling, some rehab to
12 really get that quality of life back up. So what
13 happened in the rest of the discussion is that the
14 Attorney General, you know, because you always
15 wonder what does an Attorney General have to do
16 with evidenced based medicine, and they didn't
17 look at every detail of the medicine, all they did
18 was say, well, how come the ILADS perspectives and
19 how come some of the DR.s weren't included the
20 process, why isn't there a dialogue, why did it
21 come to these kind of extreme conclusions, and so
22 why don't they get a review of the data.

1 Now, this is just the infectious
2 diseases side of America, which has had great
3 progress over the years, great promise, it's just
4 that we need some dialogue. So hopefully we'll
5 move it away from the Attorney General, back into
6 an evidenced based medicine structure.

7 So what I wanted to do is recommend that
8 instead of just the IDSA position is that we
9 include actual dialogue and include some of the
10 things ILADS has been doing, some of the things
11 we've been doing with the most complicated
12 patients, and these are the ones that are talked
13 about. So just to close up, I just wanted to show
14 you what's in the packet, is that if you look at
15 the packet, you know, as I said, I list -- I
16 included the ILADS guidelines. Sometimes when you
17 read the guidelines, nothing says that everybody
18 has to have IV therapy for prolonged -- for months
19 and years; I go to IV ten percent of the time,
20 even under my most complicated patients, so it's
21 -- it often lays out the problems in the
22 guidelines.

1 If one goes to the -- the second
2 submission is that clinical trials validate the
3 severity of persistent Lyme Disease symptoms.
4 This paper just got accepted for publication. But
5 the most important thing is that table one, which
6 is page eight of that document, it lists all 22
7 standardized instruments, and it shows not only
8 what the cases are, but the controls, the text
9 talks about how sick they are versus normal
10 populations.

11 The next submission, you know, everybody
12 would wish to have a nice economic paper, how much
13 does it cost to have a Lyme patient. This went --
14 this is a study by a CDC author, where they went
15 to Maryland, which is this area, looked at data
16 bases of people who were seen by DR.s in Maryland,
17 and they found that 95 percent of the costs were
18 not DR.s, because most of them weren't really
19 being treated. And the reason I included that is,
20 if we go to the last figure three, you don't have
21 to actually page through it, it's just that if you
22 get treated for Lyme early, it's 1,300 a year,

1 late is 16,000 a year. And the last two things
2 that are included is a generalized liability paper
3 talking about what's really wrong with making too
4 much of the NIH trials; 4.7 years is hard to
5 generalize.

6 A research letter that talks about
7 specific cases of people who had delayed
8 treatment. There's an initiative by ILADS, it's
9 to treat people early, treat more than 30 days if
10 you need to treat based on judgment, treat longer
11 than 30 if you need to, and that's captured in a
12 prevent chronic Lyme Disease type paper.

13 And so what that is is that we always
14 practice primary care, I mean primary prevention
15 is to prevent the tick and a rash from getting in
16 trouble. Tertiary prevention is like how to deal
17 with the sickest of all Lyme patients or sickest
18 of all heart patients, but we never get around to
19 secondary prevention, which is how do you prevent
20 these complicated patients. And so what I want to
21 do is, I included the Attorney General piece, but
22 I rushed through it, and I appreciate the -- just

1 letting this information get out, so when it goes
2 to Committee, they can look at this kind of
3 evidence and include it when they weigh all of
4 those factors.

5 DR. POLAND: Thank you, Dr.Cameron. I
6 believe, Mike, did you have a question?

7 DR. OXMAN: Yeah, one question; how do
8 your patients differ from patients with "chronic
9 fatigue syndrome"?

10 DR. CAMERON: In my practice, I find
11 that the list of symptoms of chronic fatigue,
12 fibromyalgia, look exactly the same. And I agree
13 with Dr.Dante from Boston, who had some dollars
14 from one of the Gulf War syndrome, the Gulf War
15 syndrome also looks the same, so it's -- anybody
16 that I treat longer than 30 days or 60 days ends
17 up having to see lots of specialists to look at
18 different views and different perspective. But if
19 you just study the symptoms, no difference.

20 DR. POLAND: Okay. Lisa, I think you
21 said we had another speaker?

22 MS. JARRETT: Yes, sir.

1 DR. POLAND: Is that speaker here?

2 MS. JARRETT: Yes; it's Commander
3 Lipsitz.

4 DR. POLAND: Would you also introduce
5 yourself and keep your statement to five minutes?

6 DR. LIPSITZ: Sure; good morning,
7 everybody. My name is Commander Rob Lipsitz, and
8 I'm a family physician, as well as a preventative
9 medicine physician who's actually pretty
10 knowledgeable in Lyme Disease based on my
11 training. Well, my grand knowledge did not
12 prevent me from being hospitalized this month at
13 Naval Hospital Bethesda for Lyme Disease.

14 So when I found out the Defense Health
15 Board was meeting, I thought it would be a good
16 opportunity to come and listen to the up-to-date
17 information as it's being presented. I just
18 wanted to ensure that the Board, when they are
19 discussing this topic, is aware of patient
20 perspective.

21 Now, I'm a physician, and as the adage
22 goes, the provider that treats himself has a fool

1 for a patient. And I thought I had an intravirus
2 syndrome, and I was getting sicker and sicker and
3 couldn't understand why.

4 And I walked into the neurology clinic,
5 where they promptly admitted me for rule out --
6 syndrome, but fortunately they had a high clinical
7 index suspicion, something I do not have, and they
8 drew antibody titers for Lyme Disease, which
9 turned out to be positive, and they started me
10 quickly on treatment, and I approved, and here I
11 am today. So I think one of the important things
12 to remember with Lyme Disease is to have a high
13 clinical index of suspicion for the disease.
14 Certainly I had risk factors. They asked me, you
15 know, are you a runner, do you go in Rock Creek
16 Park, are you active, I do all those things, so
17 that's probably how I acquired the illness.

18 So here's a physician that did not think
19 he had Lyme Disease and thought that would be way
20 out there, but the providers actually did have a
21 high clinical index, and they found it and treated
22 it. So please make sure your providers are aware

1 that in areas high risk, or even in lesser risk,
2 that they are considering Lyme Disease in their
3 differential diagnosis. That's all I had, thank
4 you.

5 DR. POLAND: Thank you, and we're glad
6 for your recovery. Thank you all for your
7 comments. Again, I would reiterate that any
8 written statements are welcome and will also be
9 reviewed by the Board. I neglected to mention one
10 other individual that I would like to help us with
11 this issue, and that's Dr. Shamoo, although has he
12 left here? He may have stepped out for a moment.
13 Colonel Gibson, did you want to make a comment?

14 COLONEL GIBSON: Yeah; we received
15 written statements from ILADS, and those will be
16 posted on the GSA web site as part of the federal
17 record. We'll post most of that right away, put
18 it up almost immediately after this meeting. Part
19 of it contained telephone numbers and email
20 addresses. We'll have to do a Privacy Act review
21 on those before they go up to make sure that we're
22 not violating anybody's privacy. After that, they

1 may end up redacting those phone numbers, et
2 cetera, and then the substance of the rest of it
3 will go up.

4 DR. POLAND: Lisa, are there any
5 other --

6 MS. JARRETT: No, sir, no, not for the
7 Lyme.

8 DR. POLAND: No, okay. Dr.Parkinson,
9 did you register?

10 DR. PARKINSON: I rarely register on
11 anything. But, no, thank you, Dr.Poland. Just a
12 thought, and it's a little -- this issue is an
13 example of what I see in expanding -- rapidly
14 expanding scope of the DHB. I mean this has been
15 an interesting meeting for me. And in light of
16 the Connecticut Attorney General's frank lawsuit
17 against a specialty society that -- and I'm now
18 the president of a specialty society, I know many
19 of you are involved in both organized medicine and
20 things like that, it has the potential to have an
21 extremely chilling effect on the potential for
22 expert opinion groups that issue recommendations.

1 And as an aside, as the DHB goes forward, and it
2 looks like the frequency and visibility of these
3 types of issues may be coming before the Board, I
4 think it's important for the Board members to
5 understand any potential liability issues, real or
6 perceived, around statements of the DHB.

7 Again, we've been doing this for years,
8 under the rubric of the AFEB for things that are
9 DOD specific, we have a public web site, our
10 information and recommendation is available. As
11 we apparently move to 150 individuals under the
12 DHB, with a wide variety of issues, in this
13 contentious area, I don't think we have to look
14 any further than our binder to see what's going on
15 out there vis-à-vis the Connecticut Attorney
16 General. So just aside, maybe it's taken care of,
17 but it rings little distal alarm bells for me
18 perhaps.

19 DR. POLAND: Dr.Silva.

20 DR. SILVA: Joe Silva; I shared with the
21 Subcommittee when we started the dig in this issue
22 that this is an enlarging process, I agree with

1 Dr.Parkinson. I used to chair for the California
2 Medical Association, a committee on scientific
3 affairs, and we used to analyze all kinds of
4 policies like this. Within a few years we had to
5 close down the committee in the process. Lawyers
6 beat the tar out of us, the CMA had its coiffeurs
7 paid out for groups that had a specific issue. So
8 this is a hot button, and I could probably name
9 another seven or eight that are just coming over
10 the hill. So we need to be on guard and we need
11 to know what our legal rights are, because we can
12 -- our body could be manipulated in ways that we
13 not -- may not foresee right now. Thank you.

14 DR. POLAND: Okay. We're going to take
15 about a five to ten minute break and then
16 reconvene, if we can, try to keep it in the five
17 minute range.

18 (Recess)

19 DR. POLAND: Okay. If members will take
20 their seats. We're running about 15 minutes
21 behind here. Our next speaker this morning is
22 Captain Robert DeMartino, who is Director of the

1 Behavioral Medicine Division within the Office of
2 the Chief Medical Officer in TRICARE Management
3 Activity. He'll provide a brief on a question
4 that was recently brought to the Board regarding
5 the issue of autism and applied behavioral
6 analysis. His presentation and slides are under
7 Tab 11. And we have scheduled 15 minutes for this
8 presentation.

9 CAPTAIN DeMARTINO: Good morning; my
10 name is Captain Robert DeMartino, I'm with the
11 Office of the Chief Medical Officer. I'm with the
12 U.S. Public Health Service and have been working
13 on issues related to autism now for maybe about
14 two years, one and a half, two years, in a variety
15 of different ways.

16 First, I would just like to -- I'm not
17 sure how familiar people are with the disorder.
18 It is a disorder in which no cause has been found.
19 In fact, if you have been watching the news
20 recently, you'll have seen that, once again, the
21 implication that vaccines are somehow responsible
22 has been sort of refuted once again in another

1 meta-analysis. That's been happening several
2 times, but there has been, over the years, a
3 number of people who have been very invested in
4 that as a cause, but so far it hasn't come
5 through. But, of course, there's nothing really
6 else to pin our hopes on just yet, although
7 there's a lot of work being done.

8 So Autism Spectrum Disorders, which were
9 sort of -- sort of comprise several disorders,
10 including autism as been described over a number
11 of years, and added to that were a couple of other
12 disorders, Retts Disorder, Childhood
13 Disintegrative Disorder, Pervasive Development
14 Disorder, are not otherwise specified. These all
15 fall within the DSM, the Diagnostic Statistical
16 Manual from the American Psychiatric Association.
17 So when we're talking about -- I'm talking about
18 ASD sort of as a group, but remember, certainly
19 there's no one cause for the disorders in this
20 group, I mean nobody is even suggesting that.

21 In addition, there's -- there are not
22 even -- the symptomatology sort of only -- in some

1 ways only marginally overlaps, so it's a bit of a
2 grab bag of groups. But the reality is that
3 between autism, Autistic Disorder, and Pervasive
4 Developmental Disorder not otherwise specified,
5 that makes up really a big portion as far as
6 prevalence for these disorders.

7 So when it's serious, it's apparent by
8 age two, often diagnosed somewhere in the three to
9 five. That number has been coming down over
10 years. And even the expression of the symptoms is
11 very variable.

12 The other disorder that I forgot to
13 mention that's in this group is Asperger's
14 Disorder, which, again, has some overlapping
15 symptoms with Autistic Disorder, but generally is
16 less serious, someone has generally much more
17 ability to lead an active life and participate in
18 activities and schooling, education. The core
19 deficits of ASD, communication, social skills,
20 deficits, and these repetitive behaviors which are
21 sort of the hallmark, I think what people sort of
22 recognize as autism, but not necessarily prevalent

1 to a large degree in every child with autism.
2 Certainly that's not necessarily a big component
3 of Asperger's Disorder, for instance. But when we
4 talk about the core deficits, we're talking for
5 the group of illnesses as a whole.

6 This slide and the next two are just
7 meant to show that in the absence of a causality,
8 and in the absence of really a definitive means of
9 addressing the symptomatology, in other words,
10 something that clearly works in a large proportion
11 of patients, reliably, there have certainly
12 emerged a number of interventions over time
13 related to this.

14 I would say that the majority of them
15 have never really been examined to any great
16 degree. A couple have been examined to a great
17 degree, some with better results and some with
18 definitively, this doesn't work. For instance,
19 sensory integration therapy has been, after a
20 number of studies, shown not to really provide a
21 clinically significant difference in symptoms.
22 But this was just to show all the things that have

1 sort of emerged over time, whether it's things
2 like chelation, vitamin therapies, secretin,
3 anti-fungals, all of these have been -- at one
4 point or another as sort of, you know, the fix for
5 the symptoms, but unfortunately, that never has
6 proven true.

7 The therapies shown at the bottom are,
8 as you know, they're not just for autism, they're
9 used in all kinds of varieties of conditions and
10 have proven to have some good effects in a limited
11 number of deficits, sort of a small number, but
12 generally not the kinds of deficits that really
13 cause the problems for children for autism, the
14 communication disorders, which really -- and some
15 of the cognitive problems.

16 Again, as I said, these next two are
17 just -- really just to give you a sense about all
18 the different things that have, you know, between
19 holding therapy and craniosacral therapy, I mean
20 just there's -- I mean it's not hard to find them.
21 If you type in Google, I mean people who are --
22 conform to these and want to practice them will

1 pop up, for better or worse.

2 On the other hand, comprehensive
3 programs, of which there are much fewer, are
4 generally collectic programs put together by
5 people who have a lot of experience in the field
6 and have sort of put together what they think
7 makes developmentally and -- the most sense. And
8 one thing characteristic of all these, most of
9 them, in one way or another, use ABA, Applied
10 Behavioral Analysis, as a -- intervention approach
11 somewhere within there, some more, to a greater
12 degree, and others to a much lesser degree. But
13 all of these use that one way or another.

14 Some of them are much better known than
15 others. TEACCH is well known; I think North
16 Carolina has incorporated that as the intervention
17 that they use, you know, state-wide, for instance,
18 and RDI has more recently been sort of been talked
19 about quite a bit more. Some of them have been
20 studied better than others.

21 So ABA, when we talk about ABA, we're
22 talking about something that came out of

1 essentially operant conditioning. Skenarian
2 conditioning, which essentially uses rewards and
3 punishments to effect change. In fact, the Lovaas
4 who did this sort of seminal studies in the '70's
5 and '80's on ABA sort of really used punishment,
6 actual physical punishment initially to get his
7 change, and he sort of -- great effects. Of
8 course, that sort of became impossible to do over
9 time, and the punishments are more, you know,
10 withdrawing things that are wanted. But, in
11 essence, it's operant conditioning, and it can --
12 it's evolved over time, it's I think become more
13 subtle, more nuanced over the years, and there's
14 been quite a bit of work in studying ABA. One of
15 the biggest problems has been the, you know, the
16 fidelity to certain models and whether the studies
17 have been done with, you know, with -- well
18 controlled and using good control groups, things
19 like that.

20 So the published studies that were
21 reviewed most recently and most comprehensibly by
22 the Institute of Medicine that was in the early

1 part of this decade essentially sort of said,
2 listen, you know, we don't -- I mean there's no
3 definitive number, we don't know that this
4 absolutely works, this one doesn't work, but their
5 sense was that more ABA was better than less ABA,
6 for the most part, and that the only study that
7 sort of gave a number was the earlier Lovaas
8 studies, in which he used 40 hours of treatment in
9 a treatment week, and he got good results.

10 So that is sort of what got carried over
11 into the IOM report. And although they said,
12 essentially, sort of over 25 seem to make the most
13 sense, and less than that, there wasn't evidence
14 that there was going to be a good effect using
15 intensive ABA, intensive meaning anything that
16 you're doing, you know, 20 or more hours a week is
17 pretty intensive, certainly. And I put this up
18 just sort of to get a clarification, because ABA
19 is really sort of a method of doing something, it
20 uses operant conditioning, but the way it gets
21 implemented, you know, looks like a lot of
22 different things. It just -- sometimes it looks

1 like sitting across a desk, giving jelly beans,
2 sometimes it's happening in an actual environment,
3 and it has to do with giving, withdrawing, things
4 that the child identifies as what they want, and
5 using those as your rewards and punishment, so it
6 doesn't always look the same, and there -- and a
7 lot of these kinds of methods have different
8 names, so there's lots of techniques that are
9 associated with ABA.

10 But at its core, the most important
11 thing is that ABA is built on a -- sort of a
12 scientific foundation of doing an analysis first
13 of behavior, applying -- and the analysis sort of
14 says what happened before the behavior that you
15 want or don't want, what can you do to change
16 that, I mean -- and then there's a feedback loop.

17 So it's, again, built on operant
18 conditioning. The methodology of ABA is founded
19 in some pretty solid, you know, it has solid
20 foundations. And as I mentioned before, because
21 it's a, you know, it's not a fixed intervention,
22 it's used -- in lots of different things, so in

1 all those comprehensive, it's used in one way or
2 the other, they don't always look the same, and in
3 many other interventions sometimes these kinds of
4 methods and techniques are used, as well. And
5 over time, they've been used for a variety of
6 things. I mean essentially anything in which you
7 want to change behavior, whether it's a speaking
8 behavior or a physical behavior or anything other
9 kind of behavior can -- is subject to operant
10 conditioning, and we've known that for decades.

11 So it's not -- I don't think anyone will
12 be surprised to know that, you know, learning to
13 learn, communication, social skills, health care,
14 academics, all those have been subject to operant
15 conditioning with the expectation that the
16 foundations of ABA are solid and they can produce
17 change.

18 And I don't think that when you look
19 through the literature, that you find studies on
20 every single one of these that would really feel,
21 you know, strongly convincing of a use. But there
22 is certainly a large body of literature at this

1 point, because a lot of these have been studied in
2 one way or another. So the issue is that the --
3 Lovaas studies in the late '80's was a relatively
4 small study in which he assigned two groups to a
5 40 hour treatment group, and one with ten hours or
6 so of treatment, and in that sense, he initially
7 sort of described it as random, but, you know, in
8 review over the years, it's been pretty clear that
9 that wasn't really a random assignment at all.

10 Now, his -- the people he worked with
11 redid those studies over time and sort of followed
12 up on them with some mixed results. And, you
13 know, this has sort of left, you know, a little
14 bit of an uncertain foundation about, you know,
15 where ABA is. I mean certainly people feel very,
16 very strongly about this, very strongly that ABA
17 is the only, at this point, definitive evidenced
18 based treatment for ABA.

19 And I think that it's sort of hard to
20 argue, because really nothing else of any
21 significance has emerged as being -- unless you
22 count pharmaceuticals that can dampen certain

1 kinds of behaviors, but if we exclude that, then
2 there's really nothing else.

3 At the same time, when we think about --
4 certainly in TRICARE, when we think about the
5 kinds of interventions that we're going to
6 support, our judgment generally has to be, is it
7 safe and is it effective, and that's -- and we
8 keep a high bar for the very reason that making
9 sure that our beneficiaries get safe and effective
10 treatment is much more -- it tends to be more
11 important in the medical sphere. Now, ABA has
12 always -- has been generally sort of conducted in
13 the educational environs, in schools, with the
14 idea mostly because this is done with very young
15 children, we're talking about the three to six or
16 seven, not much past that, with the intent of
17 getting them into school, into normal classes, if
18 possible, but at least able to learn, able to
19 integrate into their -- with their peers and move
20 on from there.

21 And so I think that one of the big
22 issues that we're interested in is knowing about,

1 you know, what do we have now, now that many years
2 have passed even since the IOM earlier in the
3 decade, a number of years have passed since then,
4 maybe with another eye looking back to see what we
5 know about ABA, what we can find out, what the
6 literature has to tell us about the short term
7 effects, about the long term effects, because, in
8 essence, I mean this is really one of the more
9 important things to know, is whether the
10 interventions that are happening in the three to
11 six year old range have -- I mean that would
12 certainly be important, if that -- if the gains
13 that are touted as being made during that time are
14 lost, you know, that's a serious problem, so
15 that's another important question. And what does
16 the literature indicate about the intensity and
17 duration of care that's beneficial, because I
18 think that's one of the most contentious issues.
19 I mean how much good ABA, if ABA is effective, how
20 much good ABA is necessary, for how many years,
21 how many hours in a week, what does the literature
22 tell us about that, you know, to achieve short

1 term and long term effects.

2 And I can tell you that the literature
3 is, you know, has a strong push towards one way of
4 thinking about that, but it remains reasonably
5 murky, murky enough to I think justify a question
6 of this sort to the Board.

7 So just to wrap up implications; so, by
8 law, ABA is -- it's not a benefit under our basic
9 TRICARE program, so it's not considered a medical
10 intervention, it's considered an educational
11 intervention that we have incorporated into a
12 special kind of a benefit, a special benefit that
13 sort of runs along side of the general medical
14 benefit, it's under a special program called the
15 ECHO Program, and it's really the only non-medical
16 intervention for autism that we -- except for, as
17 I say, occupational speech therapy that we cover.
18 And if we had -- in general it's sort of thought
19 that if we apply the same sort of rules that we
20 apply for a medical treatment, whether it be a
21 pharmaceutical treatment or a surgical
22 intervention or something like that, if we applied

1 the same kinds of standards to ABA, it probably
2 wouldn't reach the standards necessary to say,
3 hey, this is an effective medical intervention, it
4 probably would never get up to that. But we don't
5 consider it a medical intervention, we consider it
6 an educational intervention. So that's the -- I
7 guess -- I don't think I have anything else, do I,
8 no.

9 DR. POLAND: Thank you. I'd like to
10 begin open discussion, first with members of the
11 Board, and I think we do have at least one person
12 -- public comment that's registered. Dr.Blazer,
13 do you have a comment?

14 DR. BLAZER: Yes; this is Dan Blazer.
15 I'll begin with a couple of statements. One is, I
16 am not an expert in this area. I actually work in
17 the other half of the life cycle, so I do not know
18 this area well at all. What I do know is that the
19 struggle that these families go through is
20 profound, and I just want to be sure we understand
21 that this is extremely difficult for families to
22 manage. And I suspect many people around this

1 table have known families, if not their families
2 themselves, who have had to deal with these
3 problems. Having said that, what I do know from
4 the field of psychiatry at least is that this is
5 probably the hottest topic in the entire field of
6 psychiatry at the present time, as far as I know.
7 Certainly it's, from what I can tell, is the
8 hottest topic from the National Institute of
9 Mental Health. This is dominating research, it's
10 dominating trying to understand what the proper
11 therapy should be, et cetera.

12 And I guess, recognizing the charge to
13 the Board, I just think it's important for us to
14 be very cognizant that the people sitting around
15 this table may not be the best individuals to
16 answer that question. And if there were no
17 individuals trying to answer this question, that
18 would be one thing. If, in fact, there are a lot
19 of very bright people trying to address these
20 issues, I think that puts it in a somewhat
21 different perspective. So I just want to kind of
22 get that out.

1 My bottom line is, let's not try to get
2 ahead of the curve on this one too far. I
3 recognize the distinction between educational and
4 therapeutic from the perspective of ECHO, but what
5 I would note is that when you look at it as a
6 mental health professional, those two things are
7 not separated, they're part of the same. The idea
8 is, how do you help these kids to get better,
9 that's the goal, and there are a lot of people
10 trying to figure that out.

11 DR. POLAND: Dr.Parkinson, and then
12 Dr.Shamoo, and then Dr.Kaplan.

13 DR. PARKINSON: Well, Mike Parkinson;
14 every major health insurance plan, where I've
15 spent the last number of years of my life, has
16 their coverage policy decision and the process. I
17 will tell you, as anything but evidenced based,
18 despite what the five major carriers will tell you
19 that they maintain.

20 In reality, they're all hampered by a
21 flawed medical model that says that -- I mean and
22 you said it directly, nothing personal, but

1 education is not therapy. I mean education is
2 therapy when 80 percent of all disease, illness,
3 injury, and death is relating to behavior. So we
4 are saddled in DOD, as we are in the private
5 sector, by a broken paradigm along the lines that
6 Dr.Blazer just said.

7 Having said that, just so I understand
8 the process, the way the DOD works now, if I have
9 a child with autism, I automatically qualify for
10 ECHO designation, and then as a result of ECHO
11 designation, I then have access to an educational
12 program which the Department has removed from the
13 usual coverage policy decision versus, you know,
14 usual care versus "investigational", which is what
15 would occur at any health plan. It's deemed
16 investigational because we don't have the
17 criteria, therefore, it's not covered. So the
18 ECHO program and the autism within the ECHO allows
19 TRICARE to kind of say that's a different benefit,
20 but we're not going to subject it to the usual
21 TRICARE coverage policy decisions; is that clear,
22 is that -- I'm trying to piece it together and I

1 want to make sure I have that right.

2 DR. BLAZER: Well, you sort of have
3 several different issues there. Congress mandated
4 a program separate from the medical program that
5 would cover children with certain severe illnesses
6 and provide services and other things, other kinds
7 of --

8 DR. PARKINSON: Right.

9 DR. BLAZER: -- that aren't offered in
10 the medical benefit.

11 DR. PARKINSON: Okay. And the ECHO is
12 that program?

13 DR. BLAZER: Yes; and it used to be
14 called something else --

15 DR. PARKINSON: Okay.

16 DR. BLAZER: -- now it's called ECHO.

17 DR. PARKINSON: So in a way, the
18 question is kind of the wrong question as it's
19 framed by the Department, I think. The question
20 is, is there evidence that ABA is effective to
21 relieve pain, suffering, coping for families going
22 forward as opposed to using medical effectiveness

1 criteria, which we would do for a health benefit
2 plan.

3 If you've already got the ECHO
4 designation, and the Board can add value to saying
5 is the ABA a good thing to have to help families
6 cope, muddling that up a little bit with a medical
7 evidence criteria used for health benefit, which
8 is what we would do in Blue Cross or what we would
9 do in a traditional plan, say no, it doesn't meet
10 the way we do health benefits design.

11 So I'm just -- as the Board goes
12 forward, it seems like Dr.Blazer's approach to
13 this is, how can we help these families vice
14 muddling it up with does it meet scientific
15 criteria or not, because it clearly doesn't, I
16 mean it would be investigational IND you know,
17 whatever you would call it, if it went to Aetna
18 United, so the other piece of that obviously is,
19 how do all the major health plans, and there are
20 only five of them anymore that exist, how do they
21 all treat ABA therapy, that's for the Committee's
22 work, but is it deemed investigational by Blue

1 Cross Blue Shield Association and their clinical
2 policy committee, those would be useful pieces of
3 data. But it seems to me we're mixing the two in
4 the question, and we may not need to have to do
5 that to get to the outcome that Dr.Blazer is
6 talking about.

7 DR. BLAZER: I'd just like to respond to
8 that slightly, because I think -- I mean no one is
9 denying that there aren't -- we shouldn't be doing
10 things that would be benefit -- that would benefit
11 the families of this, and to that end, there are
12 certainly other things, families have access to
13 care, and there are other benefits that would do
14 that.

15 So I mean certainly it's not all the
16 eggs are in this one basket, and I don't think
17 anyone is sort of suggesting that, you know, ABA
18 is the only way that we sort of approach families,
19 you know, it's the only thing that we have right
20 now that has risen to any level in which, you
21 know, we can feel comfortable.

22 But, you know, if you look at the kinds

1 of things that parents want and would ask for, not
2 for having some standards, and we would be
3 covering hyperbaric oxygen therapy, we would be
4 carrying chelation, we would be covering, you
5 know, a whole variety of things that families feel
6 are important to do. And our job is to say,
7 listen, you know, we know that this is -- that the
8 situation is very, very difficult, but there are
9 certain things that we feel we can't do for the
10 safety of everybody, even if you feel very
11 strongly that this is something that you want.

12 DR. PARKINSON: Well, if I may just ask
13 one other clarification, because this is all just
14 clarification for the Board's work, it says that
15 the Department has launched a demonstration
16 project, so did you describe the demonstration
17 project in terms of who it is, the evaluation
18 criteria, or is this the process you want the
19 Board to help design a demonstration project?

20 DR. BLAZER: No; there's a demonstration
21 that's existing right now.

22 DR. PARKINSON: Did you present that?

1 DR. BLAZER: No, I did not.

2 DR. PARKINSON: Is that relevant to the
3 Board's work?

4 DR. BLAZER: I don't think so.

5 DR. PARKINSON: It would be my first gut
6 reaction.

7 DR. POLAND: Yeah, I think it would be.

8 Mike, I would share that opinion. But --

9 DR. BLAZER: Because it's not a
10 demonstration program to test the effectiveness of
11 an intervention, it's a service model
12 demonstration.

13 COLONEL GIBSON: Can I -- this was a
14 presentation of a question to the Defense Health
15 Board for getting that early on briefing
16 background or explaining the details of what we're
17 approaching. We have lots and lots of
18 subcommittees, we have a Psychological Health
19 Subcommittee. I would expect, and I assume that
20 Dr. Poland will say I'm assigning it to the
21 Psychological Health Subcommittee, we'll bring in
22 experts, et cetera. So does the full core Board

1 need every detail today?

2 DR. POLAND: But I think your question,
3 anything that's being done in this regard would be
4 of relevance to that subcommittee. Dr.Shamoo, you
5 had a comment?

6 DR. SHAMOO: Yeah; a question and some
7 comments. Thank you for your presentation, a nice
8 job. As you well know, autism is a whole
9 spectrum, God knows how many diseases, and it's --
10 ten years ago I became involved in looking at the
11 literature. I couldn't believe that there were
12 full professors giving conference talks which was
13 based on no science, but making conclusions
14 nevertheless. It's the worst field in terms of
15 quackery. And even NIH has fell into that
16 quackery by supporting a clinical trial with no
17 basis and fact to reach that level of a clinical
18 trial on chelation therapy. And it was shocking
19 to me that someone who's been editor and founder
20 of a journal called Accountability in Research.

21 So having said that, the ABA, it's
22 really like fate. Have you seen the people who

1 practice ABA? It's not like this may work only
2 with -- you said a spectrum with one-tenth of the
3 spectrum of 1/50th of the spectrum, they think it
4 should work with everything, and they are very
5 religious about it almost.

6 When you try to fund them through the
7 name ABA, what you are doing, you are encouraging
8 that modality of treatment for the whole spectrum.
9 You yourself said very well that ABA is really
10 behavioral mod. And why can't you just fund them
11 through generalized behavioral modification so
12 people will not be pushed into falling into one
13 modality which the data are really are not there
14 yet?

15 DR. POLAND: Thank you. There was
16 another comment, I think. Ed, and then Mark.

17 DR. KAPLAN: No, there was a comment, I
18 was raising my hand, but my question has been
19 asked by the previous -- has been answered by the
20 previous discussion.

21 DR. POLAND: Dr. Miller.

22 DR. MILLER: Mine is also a comment.

1 I'm not going to comment whether or not ABA has
2 any therapeutic effects or not. I think this
3 whole field is a -- process and I'm not convinced
4 actually that it necessarily is or isn't.

5 However, I think it's important to also
6 recognize that if these patients are receiving up
7 to 35 to 40 hours of therapy, there's a social
8 benefit to that, too, potentially a social benefit
9 that no one can deny that these families suffer
10 from the psychological aspect of dealing for the
11 entire family, and 35 to 40 hours of relief, to a
12 certain extent, of having extra help and support
13 by the therapy itself is something that we should
14 at least acknowledge is potentially important,
15 although it might not be therapeutic, it's a
16 relief for the family overall and that whole
17 psychosocial structure.

18 DR. POLAND: Thank you. Bill.

19 DR. HALPERIN: This is also a comment
20 about the complexity of this issue. One of the
21 other commissions I sit on is the Mandated Health
22 Benefits Commission for the State of New Jersey,

1 where any legislation that's going to increase the
2 coverage of -- insurance coverage, as we've just
3 heard from Mike, has to go through this
4 commission. And I'd say about half of the states
5 now have such commissions.

6 And the decisions are a combination, a
7 loose, non-formulated combination of evidence, of
8 thoughts about social benefits, about what's it
9 going to do to the cost of health insurance and
10 denial of other people.

11 So the issue is whether -- much of the
12 decision about whether TRICARE will offer this may
13 be decided by the states, whether they include it
14 as a mandated benefit if TRICARE is going to be
15 operating in those states, which gets into all
16 sorts of interesting issues of which trumps which,
17 a federal system, a state system, et cetera. So
18 it's just an issue to consider, but the decision
19 may be made by the state commissions.

20 DR. POLAND: That's a good point. Okay,
21 thank you. We're running about 30 minutes behind
22 here, and I do want to leave time -- I do want to

1 leave time for -- we have Lisa, one speaker from
2 the public?

3 MS. JARRETT: Yes; Ms. Karen Driscoll.
4 She is an autism parent and military wife.

5 DR. POLAND: Thank you. Please, yes, go
6 ahead and take the podium. And, again, if you can
7 keep your comments to under five minutes.

8 MS. DRISCOLL: Thank you. Good morning,
9 my name is Karen Driscoll, I'm a Marine Corps wife
10 and parent of a young child with autism. And I
11 think it's imperative I bring to you today the
12 parent family perspective about this devastating
13 medical disability.

14 Dr. Parkinson, you raised some excellent
15 questions that I think really focus on the impact
16 of our military families. Currently, I know you
17 had a question about the ECHO program. Currently,
18 the ECHO program has segregated ABA therapy out of
19 the TRICARE Basic program, and it's available for
20 children with severe disabilities.

21 But what that does require is that a
22 parent must enroll their child into this program.

1 So it's not a guarantee that all children with an
2 autism spectrum diagnosis actually receive ABA
3 therapy, and many children have been denied. It's
4 up to the discussion of the various managed care
5 support contractors, and there's been relatively
6 inconsistent application of this policy across the
7 three regions. So I want to highlight that to
8 you. And further, what the ECHO program then does
9 is, it places a limitation, a financial cap on a
10 child's treatment program. And so -- and that
11 current cap is at \$2,500 a month.

12 And if we look at prescribed level of
13 care for these patients, for example, a two year
14 old with a diagnosis of severe autism will go and
15 see a developmental pediatrician, and our medical
16 physicians are prescribing this care to our
17 families. They are telling families, you need to
18 be doing this for you child, and I'm telling you,
19 you need 35 to 40 hours a week.

20 Under the current autism demonstration
21 project to enhance access to care for our military
22 families, that's going to provide about ten hours

1 a week. So the limitations of the current ECHO
2 program are inadequate to meet prescribed level of
3 care, and so families are going into significant
4 debt, my family being one of them.

5 But what that really says is that for
6 our younger families and enlisted families, most
7 often these children go without. Now, in some
8 geographic regions, many families are lucky to
9 perhaps get intervention services through the
10 school district or the local state Medicaid run
11 program. But given the mobile nature of a
12 military family, inconsistent access to services
13 is a major problem. For example, when I left Camp
14 Pendleton, California, and moved to Quantico,
15 Virginia, I had a wonderful therapeutic program
16 offered part-time in the school, and they also
17 funded my home therapy treatment program.

18 My son was getting the recommended
19 standard of care 25 hours a week, which is
20 outlined as policy by the American Academy of
21 Pediatrics, as well as the National Academy of
22 Sciences with its National Research Counsel Report

1 from 2001, minimum 25 hours a week upon diagnosis.

2 So by segregating autism treatment out
3 of the TRICARE Basic program into an ECHO program,
4 it's causing delays and denial of services, and it
5 puts a financial cap on a child's prescribed
6 treatment plan, and a financial cap that does not
7 even meet the minimum recommended standard of care
8 from the American Academy of Pediatrics.

9 Now, I want to highlight a very
10 important quote from the American Academy of
11 Pediatrics 2007 Report. "The effectiveness of ABA
12 based intervention in Autism Spectrum Disorders
13 has been well documented with five decades of
14 research by using single subject methodology and
15 in controlled studies of comprehensive early
16 intensive behavior intervention programs in
17 university and community settings." The American
18 Academy of Pediatrics is telling physicians and
19 families ABA is safe and effective, and we're
20 recommending early and intensive use.

21 Now, much focus has been placed on early
22 diagnosis, rightfully so, because the earlier we

1 catch autism, the more malleable a child's brain
2 would be, and the more effective they would
3 respond to a treatment program.

4 But early diagnosis is only good when
5 treatment is received. And we will look at the
6 issues our military families experience; access to
7 care, and funding for treatment are our two main
8 barriers.

9 So when we look at how do we develop a
10 comprehensive treatment program for this patient
11 population, we need to focus on delivering that
12 service to our families. When we're living in
13 rural military communities where access to
14 intensive therapeutic programs may not be
15 available through the school district, or military
16 families are hitting bottom of wait list to bottom
17 of wait list at every single duty station,
18 effectively never getting intensive intervention.
19 So the key issues when we look at treating this
20 patient population would be, how do we get access
21 to prescribed level of care. Now, is ABA the only
22 way to go? Now, I can only speak to that

1 experience because my son has responded
2 tremendously to ABA therapy at a significant
3 financial cost to my family. But I believe there
4 are effective treatment programs, and Dr.
5 DeMartino did a wonderful job outlining the other
6 intervention programs which fall under that
7 behavior intervention category.

8 I believe the way the medical field is
9 emerging is that recommend ABA therapy; if it's
10 not proven to be effective for your child, go and
11 explore these other behavior intervention methods
12 that have shown some level of efficacy.

13 But I believe ABA has met the standard
14 of medical necessity. It's safe, it's effective,
15 and it is now the standard of care within the
16 medical community. It's supported by the National
17 Institute of Mental Health, American Academy of
18 Neurology, American Academy of Pediatrics,
19 National Academy of Sciences. At what point do we
20 say this overwhelming body of science and data is
21 adequate enough to provide access to prescribed
22 level of care for these patients? Now, one of the

1 things I'm going to be submitting to you today
2 through, I gave a copy to Lisa, is an opinion
3 letter provided to the Armed Services Committee
4 signed by various subject matter experts from
5 across the country. Most notably, we have the
6 signature of Dr.Christine Plesha Johnson. She's
7 the co- author of the 2007 American Academy of
8 Pediatric Support, and Dr.Pauline Filipek, as well
9 as a separate letter prepared by Dr.Gina Green.
10 She's one of the leading autism research experts
11 in the field today.

12 I hope you consider the information
13 provided in those letters with serious weight
14 versus the opinion that ABA is special education.
15 And I think it's very important that you recognize
16 ABA, as Dr.DeMartino outlined, behavior analysis,
17 it is not special education. We may be teaching
18 our children skills, but we're developing these
19 skills so that these children may live
20 independently, and we're providing these skills so
21 that their overall quality of life is greatly
22 improved.

1 And, Dr.Parkinson, you raised another
2 great question earlier, and recently the Journal
3 of the American Academy of Adolescent Psychiatry
4 in 2006 concluded that ABA therapy has been proven
5 effective at improving mental health of all family
6 members. And so, if I may, I just want to provide
7 a wonderful example of that. I have three
8 children, my oldest has autism. At age one, my
9 daughter was afraid of her big brother. Because a
10 child of autism doesn't often recognize that he
11 has an impact on other people around him, he's not
12 cognizant of the social skills that are necessary
13 to have a proper conversation. My son tends to
14 yell.

15 And so, as you can imagine, the strain
16 on a family when an infant is afraid of being in
17 the same room as her older brother, it hurts me,
18 it hurts my son, it hurts my daughter. And so
19 recognizing that important trouble, our therapist
20 was able to develop a treatment, or rather a
21 program we could work on as a family unit, and she
22 would help us through this to create, modify a

1 child's environment to create positive social
2 interactions between my daughter and her brother.

3 And we're also working on teaching my
4 son skills to modulate his voice, teaching social
5 skills, that's just one typical example, but it's
6 a wonderful example on how ABA can improve the
7 mental health of the family.

8 One last thing I do think it's important
9 you understand is, there are now eight states that
10 mandate coverage of autism treatment as medically
11 necessary, including speech therapy, physical
12 therapy, occupational therapy, and applied
13 behavior analysis. Twenty more states have bills
14 pending on the exact same thing. So there are now
15 many regions of the country where civilian
16 coverage of applied behavior analysis and autism
17 treatment is better than TRICARE. This is a
18 readiness issue, this is a retention issue. And
19 I'll provide this information to Lisa before I
20 leave.

21 DR. POLAND: Thank you.

22 MS. DRISCALL: I have one quick

1 important information to share. A recent FOIA
2 request has outlined that the autism incident rate
3 in the military is every one in 88 children. That
4 is active duty service members. Every one in 88
5 has a child diagnosed with autism. We need to get
6 in front of this. We need to treat these children
7 and provide them with the intensive services they
8 require so that they can lead happy, healthy, and
9 independent lives. I appreciate your leadership
10 and your openness to hear our comments today.
11 Thank you.

12 DR. POLAND: Thank you for coming. My
13 plan here is, first of all, to reiterate that any
14 written comments would be gladly received by the
15 Board and reviewed. And as Colonel Gibson
16 suggested, we're going to be assigning this topic
17 to the Psychological Health External Advisory
18 Subcommittee, who will meet and deliberate the
19 issue and bring back their recommendations to the
20 full Board for a discussion in open session. I
21 would like to ask them to please take under
22 consideration Dr. Blazer's recommendation, that we

1 be sure that that is adequately staffed with
2 subject matter experts in this particular area, so
3 thank you for that.

4 We're going to move on to new Board
5 business. Tab 14 of your meeting binders has the
6 DHB by-laws, as well as four recently signed
7 memoranda requesting the Board establish task
8 forces to address various issues, and I'll just
9 run through those.

10 One is a recent request to the Board by
11 Deputy Assistant Secretary of Defense for Force
12 Health Protection and Readiness, Ms. Embrey,
13 regarding setting up the task force in order to
14 review and provide recommendations on the manner
15 by which DOD should maintain funding and clinical
16 competency within amputee care centers in the
17 post-conflict setting, in addition to determining
18 the most appropriate infrastructure for providing
19 such care.

20 Obviously, we would expect contributions
21 from everyone on the panel on the care of
22 individuals with amputation and functional limb

1 loss. But I would also like to ask the following
2 people on the Task Force to include members of the
3 NCR BRAC Advisory Panel and Health Care Delivery
4 Subcommittee, Dr.Parkinson, Dr.Lednar, Dr.
5 Kokulis, Mr. Tobey, Mr. DuBois, and Dr.Kizer. I'd
6 also like to ask Dr.Butler from the Trauma and
7 Injury Subcommittee to be a part of this group.
8 And before I move on to that, Lieutenant General
9 LaNoue is also here and a part of that. General
10 LaNoue, would you like to make any comments?

11 GENERAL LaNOUE: I'm General LaNoue; I
12 have a unique experience in this in that in 1964,
13 when the first bombing took place in Vietnam and
14 we had our first amputee casualties being shipped
15 back to Texas, I happened to be there in the
16 residency program, and we were suddenly
17 overwhelmed with numbers of amputees that nobody
18 present had been experienced with, and it
19 presented a new problem.

20 I went off -- after a year I went off to
21 Vietnam and then came back to Valley Forge and we
22 continued to have large numbers of amputees. And

1 while I was assigned at Valley Forge General
2 Hospital, nobody there knew how to take care of
3 young, agile, robust adults who happened to be
4 missing a leg. And the policy at the time was to
5 ship them off to the VA, and I was ordered to do
6 their boards. Now, I'd have the family in their
7 weeping because they would visit the VA and they
8 would find people my age and older, alcoholics,
9 drug abusers, and they wanted to be taken care of
10 by their own, they wanted to be with their own
11 team, they wanted to be identified either as an
12 Army or Marine or a Sailor or Airman, and feel
13 that they're getting that support.

14 I might say that one of the casualties
15 was a young officer by the name of Fred Franks,
16 who's now the Chairman of our Board, and an
17 amputee, who through a more mature version of our
18 program that I happened to institute, was able to
19 return to duty and not feel that he was required
20 to sell pencils on a corner some place, which some
21 of our patients did, too.

22 And as I reviewed the history of it and

1 then watched the end of the Vietnam War and
2 watched Valley Forge Hospital close, and then I
3 moved whatever I could to Walter Reed because I
4 happened to be assigned there to try to
5 reinvigorate the amputee program, there were no
6 longer anymore casualties coming in.

7 So the history is that with every war,
8 we have certain categories of patients, amputees
9 and limb loss, functional limb loss being one of
10 them, not the only one. The first group of
11 patients come in and people say, what do we do
12 now, and they get very bad care. When I was
13 Deputy Surgeon General, I got a call from a Texas
14 billionaire with funny looking ears, and he had
15 somebody from his community who needed specialized
16 amputee care, and the hospital didn't know what to
17 do with him.

18 Right now we've got the most effective,
19 the most sophisticated, the best that's ever been
20 done in the history of science, and I'm positive
21 it's going to disintegrate as this war ends. I
22 hope the war ends. But who's going to tell me

1 that there's not going to be another war and we
2 don't go through the same cycle again.

3 The politics this time was different
4 than the last time. The politics this time said
5 we owe these men and women a return to normal life
6 and normal capability. They didn't say that when
7 I was doing it. I was almost court marshaled for
8 keeping patients under my care against orders,
9 because the families really wanted to be cared for
10 by us, and that will happen again. Whether it's a
11 war with Russia or Ossetia or wherever we might go
12 the next time around, there will be another war,
13 we will have the need, and we need a bridge to
14 maintain our capability. I don't know what that
15 bridge is, but we need to look for it.

16 DR. POLAND: Thank you, and a good set
17 up for why this is such an important issue for
18 this subcommittee. I would also like to ask that
19 the clinical and program policy, as well as FHP
20 and R provide experts to contribute strategic
21 input to this question. The services and TRICARE
22 Management Activity should also designate a

1 representative to assist the panel, including TMA
2 budget representatives. And I would also ask that
3 the Department of Veteran Affairs be involved in
4 the Task Force deliberations, and perhaps we can
5 get a -- the Task Force can provide a brief to us
6 at our next full Board meeting in December.

7 In addition to the memorandum requiring
8 sustainment of clinical competency and funding for
9 amputee and functional limb loss patient care,
10 there are also three memoranda signed by the
11 Assistant Secretary of Defense for Health Affairs,
12 Dr.Casscells, which requests the Board establish
13 three additional Task Force.

14 One is a Task Force on nutrition, which
15 will be established in order to provide a review
16 of DOD initiatives pertaining to nutrition and
17 health promotion within contingency environments
18 and offer policy and research recommendations
19 which address various nutritional issues with the
20 goal of optimizing physical and mental performance
21 of service members, especially during combat and
22 within military training environments. The idea

1 is that this Task Force would specifically focus
2 on the nutritional composition of diets, use of
3 dietary supplements, the impact of nutrition on
4 immune status and performance, and current
5 research within the Department concerning enhanced
6 diets for service members.

7 Another Task Force will assess the scope
8 and structure of DOD health related research in
9 order to provide the Department with
10 recommendations regarding enhancing and improving
11 health research to make it more efficient and
12 effective while maintaining alignment with the
13 Department's vision and priorities. The
14 Deployment Health Research External visit
15 highlighted the need for something like this.

16 Of particular focus that has come up is
17 the review of regenerative medicine research and
18 best practices. Current research efforts within
19 the Department require streamlining and
20 coordination since various departmental agencies
21 conduct research which covers a very broad scope,
22 relies on multiple funding streams, and is carried

1 out in concert with academic institutions,
2 consortia, and other research entitles. As a
3 result, there's a critical need to mitigate and
4 resolve the difficulties which stem from those
5 complexities and exacerbate the identification and
6 resolution of any health research gaps.

7 Finally, an additional Task Force that's
8 been requested is to assess the scope and
9 structure of DOD medical stability operations,
10 including the review of education and training of
11 relief providers. Lessons learned from events
12 such as Hurricane Katrina illustrated the urgent
13 need for the Department's involvement in stability
14 operations and disaster response.

15 DOD doctrine has recently been amended
16 to characterize stability operations as a core
17 competency of the U.S. Military and equivalent
18 with combat operations. The Task Force will
19 specifically focus on addressing metrics,
20 contingency planning, and logistics of integrating
21 medical stability assistance across all
22 departmental activities and should consider

1 communication, outreach, and coordination efforts
2 -- aspects of such efforts.

3 Dr.Casscells will be nominating members
4 to serve on these Task Forces. Core Board members
5 who wish to serve on these Task Forces may do so,
6 as well. In addition, subcommittee members who
7 have particular interest in any of these are
8 eligible to participate, so please let us know if
9 you are -- have interest there. There's also been
10 a Work Group on Information Management and
11 Information Technology developed under the Health
12 Care Delivery Subcommittee, which will examine
13 issues pertaining to Information Management and
14 Information Technology infrastructure, as well as
15 that interface between DOD and DBA.

16 So any particular questions about any of
17 those task forces or aspects? If not, then I
18 think we will adjourn the Board and go into
19 Executive Session. Ms. Embrey, can you adjourn
20 the Board's business meeting, please?

21 MS. EMBREY: My pleasure; this meeting
22 of the Defense Health Board is adjourned. Thank

1 you for your work and thank you for coming.

2 (Whereupon, at 11:54 a.m., the

3 PROCEEDINGS were adjourned.)

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3 I, Carleton J. Anderson, III do hereby certify
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17 in and for the Commonwealth of Virginia

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